



PATENT
Docket No. 56842US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s): Mittelstadt et al.) Group Art Unit: 3772
)
Serial No.: 09/888,943) Examiner: Nihir B. Patel
Confirmation No.: 9282)
)
Filed: 25 June 2001)
)
For: RESPIRATOR VALVE

APPEAL BRIEF

Commissioner for Patents
Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief is presented in support of the Appeal filed 1 October 2008, from the final rejection of claims 27-47, 49-69, and 71 of the above-identified application under 37 C.F.R. §§1.113 and 1.191.

This Brief is being submitted as set forth in 37 C.F.R. §41.37. Please charge Deposit Account No. 13-4895 the fee for filing this Brief under 37 C.F.R. §41.20(b)(2).

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I. REAL PARTY IN INTEREST

The real party in interest of the above-identified patent application is the assignee, 3M Innovative Properties Company, as evidenced by the assignment recorded at Reel 0011954, Frame 0746 on 26 June 2001.

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II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to Appellants' Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-18 were filed in this application. Claims 1-14 were canceled and claims 19-47 were added in the Amendment and Response filed 19 October 2004. Claims 48-50 were added in the Amendment and Response filed 26 July 2006. Claims 15-26 and 48 were canceled and claims 51-69 and 71 were added in the Amendment and Response filed 31 October 2007 (note: claim 70 was inadvertently omitted in the Amendment and Response).

Claims 27-47, 49-69, and 71 are pending and are the subject of this appeal (see Claim Appendix).

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IV. STATUS OF AMENDMENTS.

No claim amendments have been presented since issuance of the Final Rejection dated 27 June 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER.

With reference to Figures 1-4, one embodiment of the invention as recited in independent claim 28 is a respirator having a unidirectional valve. The respirator (e.g., respirator 10, *see Specification*, page 3, line 30 to page 4, line 7) includes: a face mask (e.g., face piece 12, *see Specification*, page 3, line 31 to page 5, line 16) having at least one opening (e.g., opening 18, *see Specification*, page 3, line 31 to page 4, line 7, page 5, lines 13-16) for receiving a unidirectional valve; and a unidirectional valve (e.g., exhalation valve assembly 20, *see Specification*, page 3, line 31 to page 4, line 2, page 5, lines 13-22). The unidirectional valve (e.g., exhalation valve assembly 20) includes: a valve body (e.g., frame 50, *see Specification*, page 5, line 16 to page 6, line 2) comprising a valve opening (e.g., opening or orifice 52, *see Specification*, page 5, line 16 to page 6, line 2); and a valve flap (e.g., valve diaphragm 56, *see Specification*, page 5, line 16 to page 6, line 16) having a first portion (e.g., connectors 80, *see Specification*, page 6, line 24 to page 7, line 32) attached to the valve body (e.g., frame 50) and an adjacent second portion (e.g., flap portion 70, *see Specification*, page 6, lines 3-23) that seals the valve opening (e.g., opening or orifice 52), wherein the valve flap (e.g., valve diaphragm 56) has a curvature from a first end (e.g., first end 76, *see Specification*, page 6, lines 3-16) to a second end (e.g., second end 77, *see Specification*, page 6, lines 3-16) when the valve flap (e.g., valve diaphragm 56) is not attached to the valve body (e.g., frame 50), and further wherein at least a portion of the curvature of the valve flap (e.g., valve diaphragm 56) is at least partially flattened (e.g., *see Specification*, page 6, lines 11-16, page 11, lines 1-15) when the valve flap (e.g., valve diaphragm 56) seals the valve opening (e.g., opening or orifice 52).

Another embodiment of the invention as recited in independent claim 38 is a respirator. The respirator (e.g., respirator 10, *see Specification*, page 3, line 30 to page 4, line 7) includes: a face mask (e.g., face piece 12, frame 50, *see Specification*, page 3, line 31 to page 6, line 2) including an opening (e.g., opening 18, *see Specification*, page 3, line 31 to page 4, line 7, page 5, lines 13-16) formed therethrough and a unidirectional valve (e.g., exhalation valve assembly 20, *see Specification*, page 3, line 31 to page 4, line 2, page 5, lines 13-22) located over the

opening (e.g., opening 18) in the face mask (e.g., face piece 12, frame 50). The unidirectional valve (e.g., exhalation valve assembly 20) includes a valve flap (e.g., valve diaphragm 56, *see Specification*, page 5, line 16 to page 6, line 16) attached to the face mask (e.g., face piece 12, frame 50) over the opening (e.g., opening 18), the valve flap (e.g., valve diaphragm 56) comprising a curvature from a first end (e.g., first end 76, *see Specification*, page 6, lines 3-16) to a second end (e.g., second end 77, *see Specification*, page 6, lines 3-16) when the valve flap (e.g., valve diaphragm 56) is not attached to the face mask (e.g., face piece 12, frame 50), wherein the curvature of the valve flap (e.g., valve diaphragm 56) is at least partially flattened (e.g., *see Specification*, page 6, lines 11-16, page 11, lines 1-15) when the valve flap (e.g., valve diaphragm 56) seals the opening (e.g., opening 18) in the face mask (e.g., face piece 12, frame 50).

Still another embodiment of the invention as recited in independent claim 51 is a respirator including a unidirectional valve. The respirator (e.g., respirator 10, *see Specification*, page 3, line 30 to page 4, line 7) includes: a face mask (e.g., face piece 12, *see Specification*, page 3, line 31 to page 5, line 16); and a unidirectional valve (e.g., exhalation valve assembly 20, *see Specification*, page 3, line 31 to page 4, line 2, page 5, lines 13-22) attached to the face mask (e.g., face piece 12) over an opening (e.g., opening 18, *see Specification*, page 3, line 31 to page 4, line 7, page 5, lines 13-16) formed through the face mask (e.g., face piece 12). The unidirectional valve (e.g., exhalation valve assembly 20) includes: a valve body (e.g., frame 50, *see Specification*, page 5, line 16 to page 6, line 2) comprising a valve opening (e.g., opening or orifice 52, *see Specification*, page 5, line 16 to page 6, line 2); and a cantilevered valve flap (e.g., valve diaphragm 56, *see Specification*, page 5, line 16 to page 6, line 16) comprising a first end (e.g., first end 76, *see Specification*, page 6, lines 3-16) attached to the valve body (e.g., frame 50) and a second end (e.g., second end 77, *see Specification*, page 6, lines 3-16) located opposite from the first end (e.g., first end 76). The first end (e.g., first end 76) of the valve flap (e.g., valve diaphragm 56) is attached to the valve body (e.g., frame 50) outside of the valve opening (e.g., opening or orifice 52), and wherein the valve flap (e.g., valve diaphragm 56) comprises a curvature from the first end (e.g., first end 76) to the second end (e.g., second end 77) when the

valve flap (e.g., valve diaphragm 56) is not attached to the valve body (e.g., frame 50), and further wherein at least a portion of the curvature of the valve flap (e.g., valve diaphragm 56) is at least partially flattened (e.g., *see Specification*, page 6, lines 11-16, page 11, lines 1-15) when the valve flap (e.g., valve diaphragm 56) seals the valve opening (e.g., opening or orifice 52).

Yet still another embodiment of the invention as recited in independent claim 61 is a respirator. The respirator (e.g., respirator 10, *see Specification*, page 3, line 30 to page 4, line 7) includes: a face mask (e.g., face piece 12, frame 50, *see Specification*, page 3, line 31 to page 6, line 2) comprising an opening (e.g., opening 18, *see Specification*, page 3, line 31 to page 4, line 7, page 5, lines 13-16) formed therethrough; and a unidirectional valve (e.g., exhalation valve assembly 20, *see Specification*, page 3, line 31 to page 4, line 2, page 5, lines 13-22) located over the opening (e.g., opening 18) in the face mask (e.g., face piece 12, frame 50). The unidirectional valve (e.g., exhalation valve assembly 20) includes a cantilevered valve flap (e.g., valve diaphragm 56, *see Specification*, page 5, line 16 to page 6, line 16) comprising a first end (76) attached to the face mask (e.g., face piece 12, frame 50), wherein the cantilevered valve flap (e.g., valve diaphragm 56) extends over the opening (e.g., opening 18). The cantilevered valve flap (e.g., valve diaphragm 56) includes a curvature from the first end (e.g., first end 76, *see Specification*, page 6, lines 3-16) to a second end (e.g., second end 77, *see Specification*, page 6, lines 3-16) when the cantilevered valve flap (e.g., valve diaphragm 56) is not attached to the face mask (e.g., face piece 12, frame 50), wherein the curvature of the cantilevered valve flap (e.g., valve diaphragm 56) is at least partially flattened (e.g., *see Specification*, page 6, lines 11-16, page 11, lines 1-15) when the valve flap (e.g., valve diaphragm 56) seals the opening (e.g., opening 18) in the face mask (e.g., face piece 12, frame 50).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. The rejection of claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 under 35 U.S.C. §102(b) as being anticipated by Lübeck (DE 1213249).
- B. The rejection of claims 33, 43, 56, and 66 under 35 U.S.C. §103(a) as being unpatentable over Lübeck (DE 1213249) in view of Japuntich et al. (U.S. Patent No. 5,509,436)

VII. ARGUMENT

A. Claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 are not anticipated under 35 U.S.C. §102(b) by Lübeck (DE 1213249).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Appellants assert that, for at least the reasons presented below, Lübeck fails to teach each and every element of rejected claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 as required for a proper rejection based on anticipation, and thus, Appellants request review and reversal of this rejection by the Board.

1. Lübeck does not teach a valve flap having a curvature that is at least partially flattened when the valve flap seals an opening (Claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71).

In spite of the assertions to the contrary by the Examiner, Lübeck does not teach that at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening or opening in the face mask as recited in independent claims 28, 38, 51, and 61. As a result, Lübeck cannot anticipate claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71.

In response to Appellants' arguments presented with regard to this issue, the Examiner has asserted that "Figure 5 shows that at least a portion of the curvature of the valve flap is at least partially flattened [sic] when the valve flap seals the valve opening." *Advisory Action*, 6 August 2008, page 2. Figure 5 of Lübeck (as reproduced below), however, does not show a valve flap having at least a portion of the curvature at least partially flattened when the valve flap seals an opening as asserted by the Examiner.

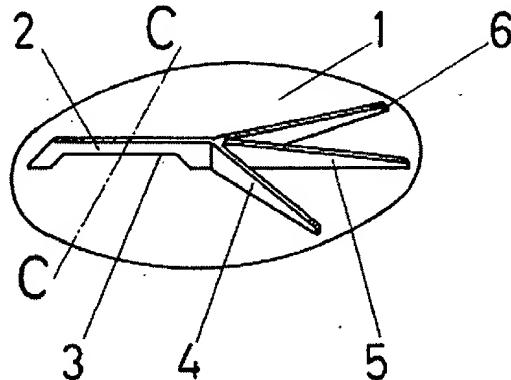
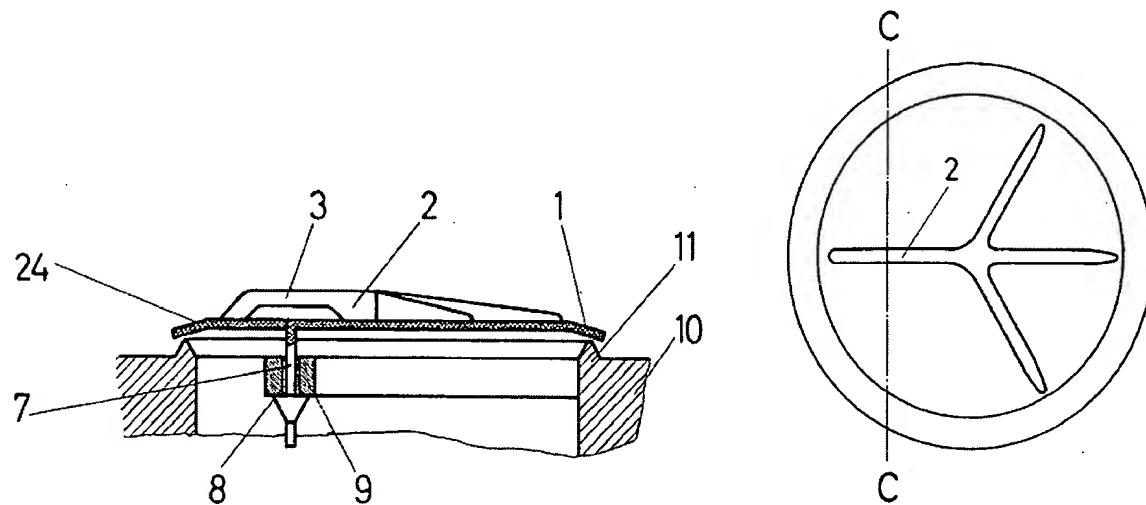


Figure 5 of Lübeck

Despite the Examiner's assertions, no portion of Figure 5 depicts a valve flap having curvature that is at least partially flattened as recited in independent claims 28, 38, 51, and 61. Rather, Figure 5 is a perspective view of a normally-flat valve flap that is closed. At best, it appears that the lip extending around the entire perimeter of the valve flap as shown in Figures 1 and 2 of Lübeck (reproduced below) is not included in the view of Figure 5 (as at least partially evidenced by the disparate proximity of the outward ends of the ribs 2 and 4-6 to the perimeter of the flap in Figure 5 as compared to Figures 1 and 2).



Figures 1 & 2 of Lübeck

Figure 6 of Lübeck (reproduced below) further supports Appellants' interpretation because Figure 6 is described as depicting the valve flap of Figure 5 in an unsealed or open state (i.e., deflected into a bent shape by air pressure to open the valve when, e.g., a user exhales). *Lübeck Translation*, page 3, line 5. As shown, the lip depicted in Figures 1-2 is also missing from Figure 6. If the missing lip was depicted as being flattened in Figure 5, then at least the portion of the lip that was raised off of the valve seat would be expected to resume its normal orientation in Figure 6 – but no such lip is depicted (see below).

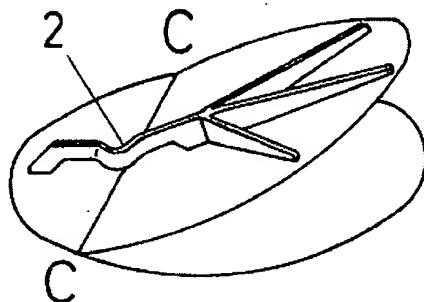


Figure 6 of Lübeck

As a result, the only logical conclusion is that Figure 5 does not include the lip and, therefore, *Lübeck* does not anticipate claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 because it does not disclose a curved valve flap in which at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening or opening in the face mask as recited in independent claims 28, 38, 51, and 61.

In view of the failure of Lübeck to explicitly teach a partially flattened valve flap as recited in claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71, the Examiner must be relying on the unstated assertion that Lübeck inherently teaches the missing features, i.e., the Examiner must be relying on the legal doctrine of inherency to support this anticipation rejection.

The requirements for an anticipation rejection based on inherency have not, however, been met.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. §2112(IV), p. 2100-47, 8th Ed., Rev. 6, (Sept. 2007) (emphasis in original) (*citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999). *See also* M.P.E.P. §2112(IV), p. 2100-47, 8th Ed., Rev. 6, (Sept. 2007). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). *See also* M.P.E.P. §2112(IV), p. 2100-48, 8th Ed., Rev. 6, (Sept. 2007).

For a proper anticipation rejection based on inherency, the Examiner must show, by fact or technical reasoning, that the valve flaps disclosed in Lübeck necessarily have curvature from a first end to a second end when not attached, wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening or opening in the face mask. No such facts or reasoning have, however, been provided.

In particular, the Examiner has failed to identify any facts or provide any credible reasoning to establish that the valve flaps of Lübeck necessarily have curvature from a first end to a second end when not attached, wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening or opening in the face mask as would be as required for an anticipation rejection based on inherency.

Further, under the doctrine of inherency, the alleged inherent characteristic of Lübeck (i.e., that the valve flap(s) necessarily have a curvature from a first end to a second end when not attached that is at least partially flattened as discussed above) may not be established by probabilities or possibilities. *See In re Robertson*, 169 F.3d at 745, 49 U.S.P.Q.2d at 1950-51. *See also* M.P.E.P. §2112(IV), p. 2100-47. As a result, even if it is determined that the valve flaps

of Lübeck may have curvature that is at least partially flattened when the valve flap seals the valve opening or opening in the face mask as recited in claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71, that finding would not satisfy the requirement for a rejection based on inherency because it cannot "reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d at 1464 (emphasis in original). *See also* M.P.E.P. §2112(IV), p. 2100-48.

For at least this reason, Appellants submit that the anticipation rejection of claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 is improper and request its review and reversal by the Board.

2. Lübeck does not teach a valve flap having a curvature from a first end to a second end when not attached to a valve body or face mask (Claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71).

Another basis for review and reversal of the anticipation rejection of claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 by the Board is the failure of Lübeck to teach a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask as recited in independent claims 28, 38, 51, and 61. Lübeck, instead, teaches valve flaps that have a flat center portion and a lip that extends around the perimeter of the flat center portion with the lip being oriented at an angle with respect to the flat center portion. *See, e.g., Lübeck*, Figure 1 (reproduced below).

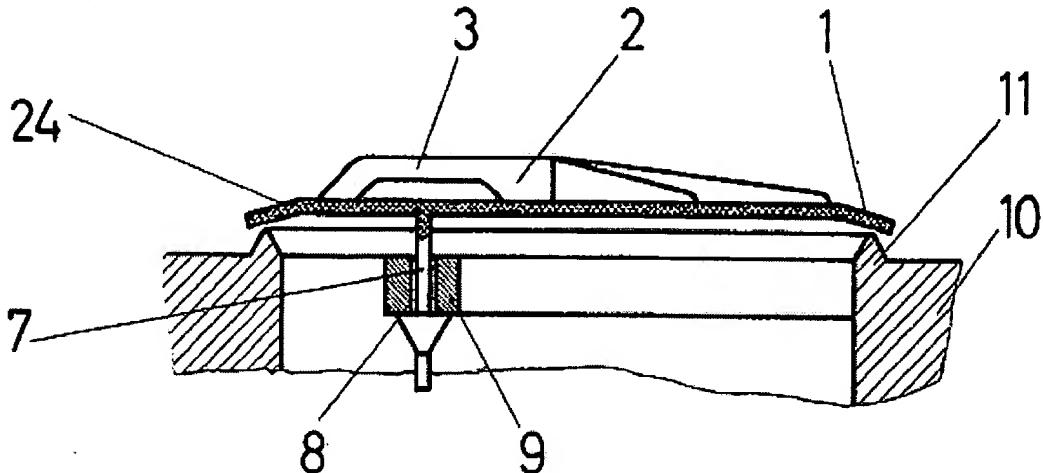


Figure 1 of Lübeck

In response to Appellants' arguments regarding this issue during prosecution, it has been asserted in the Final Office Action and the Advisory Action that "Figure 1 of Lübeck reference shows a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask (the spots where reference characters 1 and 24 are pointing at define a curvature from the first end 24 to the second end 1)." *Final Office Action*, 27 June 2008, page 2; *Advisory Action*, 6 August 2008, page 2. Appellants respectfully disagree.

Figure 1 of Lübeck, as reproduced above, shows that the portions 1 and 24 (as identified by the Examiner) merely depict a lip that is angled downward from and that extends around the perimeter of the flat center portion of the valve flap as opposed to a curvature from a first end to a second end. Furthermore, the valve flap depicted in Figure 1 is clearly attached to a valve support structure (e.g., using pin 7 inserted into the hole 8 of support 9 of the valve closure body, which is in turn connected to the valve support 10). In other words, Figure 1 of Lübeck does not depict a valve flap that is "not attached" to some support structure. As a result, Figure 1 of Lübeck does not support the assertion that Lübeck teaches a valve flap having a curvature from a first end to a second end when the flap is not attached to a valve body or a face mask as recited in independent claims 28, 38, 51, and 61 because the flap depicted in Figure 1 does not include the recited curvature, nor does Figure 1 depict a valve flap that is not attached to support structure.

Further, the remainder of the figures and disclosure of Lübeck does not teach a valve flap having a curvature from a first end to a second end. Instead, Figures 2-6 are merely different views of the same valve flap of Figure 1 having a flat center portion and flat lip extending around the perimeter (note: Figures 3-6 appear to be missing the lip surrounding the perimeter of the valve flap described herein) and Figure 7 is a different embodiment with a flat valve flap. *See Lübeck Translation*, page 3.

Also, nothing within Lübeck teaches a valve flap having a curvature from a first end to a second end when not attached. It has been asserted during prosecution that the "last paragraph on page 1" of Lübeck remedies this deficiency. *See Final Office Action*, 27 June 2008, page 3. Appellants respectfully disagree. The last paragraph of page 1 of Lübeck (reproduced below) does not remedy this deficiency.

An inhalation valve for respirator masks is furthermore known, whose valve seat is made up of the wall of the mask body and covered by a rubber disc forming the closure body, which is attached along its centerline on both sides of the mask wall.

Lübeck Translation, last paragraph of page 1.

In brief, the last paragraph of page 1 of Lübeck merely states that a valve flap "is attached" and does not provide any support for the assertion that Lübeck teaches anything regarding the curvature of the valve flap "when not attached." Further, the remainder of Lübeck does nothing to remedy this deficiency (i.e., nothing within the disclosure of Lübeck teaches a valve flap having a curvature when not attached).

As a result, neither Figure 1 (as cited by the Examiner), the last paragraph of page 1 (as cited by the Examiner), nor the remainder of Lübeck support the assertion that Lübeck teaches a valve flap having or comprising a curvature from a first end to a second end when not attached to the valve body or the face mask as recited in independent claims 28, 38, 51, and 61. For at least this reason, Appellants submit that the anticipation rejection of claims 27-32, 34-42, 44-55, 57-65, 67-69, and 71 is improper and request its review and reversal by the Board.

3. Lübeck does not teach a cantilevered valve flap (Claims 51-55, 57-65, 67-69, and 71).

Another basis for review and reversal of the anticipation rejection of claims 51-55, 57-65, 67-69, and 71 by the Board is the failure of Lübeck to teach a cantilevered valve flap as recited in independent claims 51 and 61. Lübeck, instead, teaches valve flaps that are attached within a support structure at an intermediate location. *See, e.g., Lübeck, Figures 1 & 7 (reproduced below).* As a result, Lübeck does not teach a cantilevered valve flap as recited in claims 51-55, 57-65, 67-69, and 71.

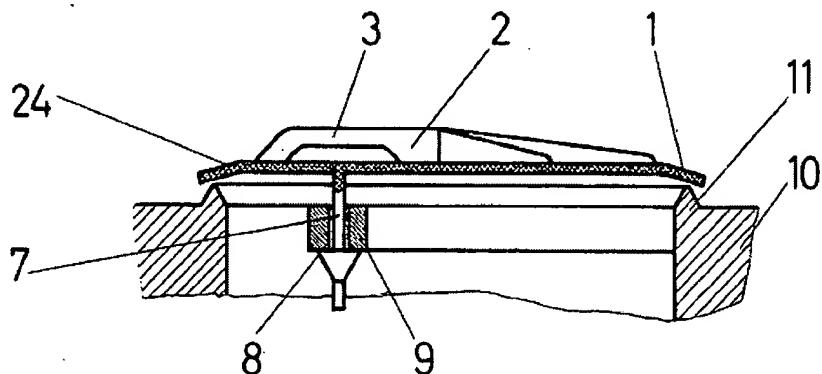


Figure 1 of Lübeck

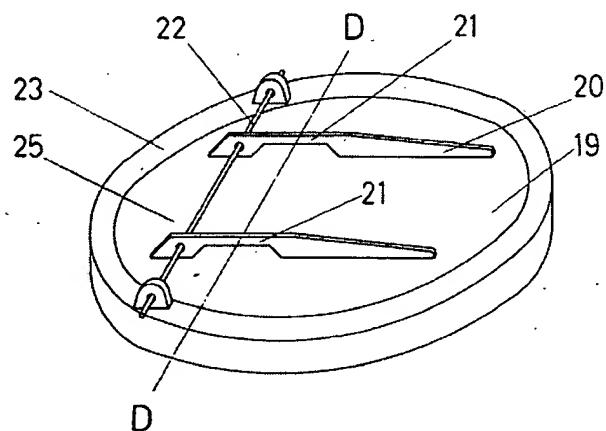


Figure 7 of Lübeck

The recitation of a cantilevered valve flap as recited in claims 51-55, 57-65, 67-69, and 71 has not been specifically addressed by the Examiner in any of the rejections presented during prosecution of this application.

The lack of any teaching of a cantilevered valve flap demonstrates another reason why Lübeck cannot form the basis for an anticipation rejection of claims 51-55, 57-65, 67-69, and 71. For at least this reason, Appellants submit that the anticipation rejection of claims 51-55, 57-65, 67-69, and 71 is improper and request its review and reversal by the Board.

B. Claims 33, 43, 56, and 66 are not obvious under 35 U.S.C. §103(a) over Lübeck (DE 1213249) in view of Japuntich et al. (U.S. Patent No. 5,509,436).

The Examiner has failed to establish a *prima facie* case of obviousness for claims 33, 43, 56, and 66 over Lübeck in view of Japuntich et al. As a result, Appellants respectfully request review and reversal of this rejection by the Board.

Lübeck, as admitted in the Final Office Action, does not disclose "a facemask that is formed of a filtering material." *Final Office Action*, 27 June 2008, page 7. Japuntich has been presented to "provide a facemask that is formed of a filtering material." *Final Office Action*, 27 June 2008, page 7.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1970). Appellants respectfully submit that Lübeck and Japuntich et al., taken alone or together, do not teach or suggest each and every element of claims 16-17 and, as a result, a *prima facie* case of obviousness has not been established.

As demonstrated above with respect to the anticipation rejection of independent claims 28, 38, 51, and 61, Lübeck does not teach all of the features recited in those claims. Nor has any credible assertion been made that the missing elements are suggested by Lübeck. Japuntich et al. does not cure the deficiencies of Lübeck, and also, is cited only for its teachings with respect to filtering face masks. In making this obviousness rejection, the Examiner has not identified why

or how one of ordinary skill in the art would modify the teachings of Lübeck in view of Japuntich et al. to reach the inventions recited in claims 33, 43, 56, and 66 (each of which directly depends on one of independent claims 28, 38, 51, and 61) as would be required to establish a *prima facie* case of obviousness with respect to those claims.

For at least these reasons, Appellants submit that a *prima facie* case of obviousness has not been established with respect to 33, 43, 56, and 66 over Lübeck in view of Japuntich. Review and reversal of this obviousness rejection of claims 33, 43, 56, and 66 are, therefore, respectfully requested.

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VIII. SUMMARY

For the foregoing reasons, Appellant respectfully requests that the Board review and reverse the rejections of claims 27-47, 49-69, and 71 as discussed herein and that notification of the allowance of these claims be issued.

Respectfully submitted by

Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581336
Minneapolis, MN 55458-1336
(612)305-1220

19 DEC. 2008
Date

By: 
Kevin W. Raasch
Reg. No. 35,651
Direct Dial: (612) 305-1218

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By: Dani Maro
Name: Dani Maro

CLAIMS APPENDIX
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27. The respirator of claim 28, wherein the valve flap is removably attached to the valve body.
28. A respirator having a unidirectional valve, comprising:
 - a face mask having at least one opening for receiving a unidirectional valve; and
 - a unidirectional valve comprising:
 - a valve body comprising a valve opening; and
 - a valve flap having a first portion attached to the valve body and an adjacent second portion that seals the valve opening, wherein the valve flap has a curvature from a first end to a second end when the valve flap is not attached to the valve body, and further wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening.
29. The respirator of claim 28, wherein the valve opening is generally planar, and wherein the valve flap curvature biases the valve flap toward the valve opening when the valve flap is attached to the valve body to seal the valve opening.

30. The respirator of claim 28, wherein the valve flap curvature biases the valve flap toward the valve opening to seal the valve opening, and wherein the bias of the valve flap toward the valve opening is sufficient to seal between the valve opening in any orientation of the unidirectional valve.
31. The respirator of claim 28, wherein the curvature in the valve flap comprises a constant curvature from the first end to the second end.
32. The respirator of claim 28, wherein the curvature in the valve flap varies from the first end to the second end.
33. The respirator of claim 28, wherein the face mask is formed of a filtering material.
34. The respirator of claim 28, wherein the unidirectional valve is an exhalation valve.
35. The respirator of claim 28, wherein the unidirectional valve is an inhalation valve.
36. The respirator of claim 28, wherein the valve flap further comprises a top surface, a bottom surface, at least one support element extending from the top surface of the valve flap, and

wherein the at least one support element provides the curvature in the valve flap that is at least partially flattened when the valve flap seals the valve opening.

37. The respirator of claim 28, wherein the valve flap further comprises a top surface, a bottom surface, wherein the valve flap further comprises a plurality of support elements extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support element, and wherein the plurality of support elements provide the curvature in the valve flap that is at least partially flattened when the valve flap seals the valve opening.

38. A respirator comprising:
a face mask comprising an opening formed therethrough; and
a unidirectional valve located over the opening in the face mask, the unidirectional valve comprising a valve flap attached to the face mask over the opening, the valve flap comprising a curvature from a first end to a second end when the valve flap is not attached to the face mask, wherein the curvature of the valve flap is at least partially flattened when the valve flap seals the opening in the face mask.

39. The respirator of claim 38, wherein the at least partially flattened curvature of the valve flap creates a bias that is substantial enough to keep the valve flap sealed over the opening in all orientations.
40. The respirator of claim 38, wherein the curvature of the valve flap comprises a constant curvature.
41. The respirator of claim 38, wherein the curvature of the valve flap varies from the first end to the second end.
42. The respirator of claim 38, wherein the opening is generally planar such that the curvature of the valve flap attached to the face mask over the opening is flattened when the valve flap seals the opening in the face mask.
43. The respirator of claim 38, wherein the face mask is formed of a filtering material.
44. The respirator of claim 38, wherein the unidirectional valve is an exhalation valve.
45. The respirator of claim 38, wherein the unidirectional valve is an inhalation valve.

46. The respirator of claim 38, wherein the valve flap further comprises a top surface, a bottom surface, and at least one support element extending from the top surface of the valve flap, wherein the at least one support element provides the curvature in the valve flap that is at least partially flattened when the valve flap seals the opening.

47. The respirator of claim 38, wherein the valve flap further comprises a top surface, a bottom surface, wherein the valve flap further comprises a plurality of support elements extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support element, and wherein the plurality of support elements provide the curvature in the valve flap that is at least partially flattened when the valve flap seals the valve opening.

49. The respirator of claim 28, wherein the valve flap comprises a cantilevered valve flap, and wherein the first portion of the valve flap is attached to the valve_body outside of the valve opening.

50. The respirator of claim 38, wherein the valve flap comprises a cantilevered valve flap, and wherein the first end of the cantilevered valve flap is attached to the face mask.

51. A respirator including a unidirectional valve, the respirator comprising:

a face mask; and

a unidirectional valve attached to the face mask over an opening formed through the face mask, wherein the unidirectional valve comprises:

a valve body comprising a valve opening; and

a cantilevered valve flap comprising a first end attached to the valve body

and a second end located opposite from the first end, wherein the first end of

the valve flap is attached to the valve body outside of the valve opening, and

wherein the valve flap comprises a curvature from the first end to the second

end when the valve flap is not attached to the valve body, and further wherein

at least a portion of the curvature of the valve flap is at least partially flattened

when the valve flap seals the valve opening.

52. The respirator of claim 51, wherein the valve opening is generally planar, and wherein the valve flap curvature biases the valve flap toward the valve opening when the valve flap is attached to the valve body to seal the valve opening.

53. The respirator of claim 51, wherein the valve flap curvature biases the valve flap toward the valve opening to seal the valve opening, and wherein the bias of the valve flap toward the valve opening is sufficient to seal between the valve opening in any orientation of the unidirectional valve.

54. The respirator of claim 51, wherein the curvature in the valve flap comprises a constant curvature from the first end to the second end.

55. The respirator of claim 51, wherein the curvature in the valve flap varies from the first end to the second end.

56. The respirator of claim 51, wherein the face mask is formed of a filtering material.

57. The respirator of claim 51, wherein the unidirectional valve is an exhalation valve.

58. The respirator of claim 51, wherein the unidirectional valve is an inhalation valve.

59. The respirator of claim 51, wherein the valve flap further comprises a top surface, a bottom surface, at least one support element extending from the top surface of the valve flap, and wherein the at least one support element provides the curvature in the valve flap that is at least partially flattened when the valve flap seals the valve opening.

60. The respirator of claim 51, wherein the valve flap further comprises a top surface, a bottom surface, wherein the valve flap further comprises a plurality of support elements extending from the top surface, wherein each of the plurality of support elements is spaced from

each adjacent support element, and wherein the plurality of support elements provide the curvature in the valve flap that is at least partially flattened when the valve flap seals the valve opening.

61. A respirator comprising:

a face mask comprising an opening formed therethrough; and

a unidirectional valve located over the opening in the face mask, the unidirectional valve comprising a cantilevered valve flap comprising a first end attached to the face mask, wherein the cantilevered valve flap extends over the opening, the cantilevered valve flap comprising a curvature from the first end to a second end when the cantilevered valve flap is not attached to the face mask, wherein the curvature of the cantilevered valve flap is at least partially flattened when the valve flap seals the opening in the face mask.

62. The respirator of claim 61, wherein the at least partially flattened curvature of the cantilevered valve flap creates a bias that is substantial enough to keep the cantilevered valve flap sealed over the opening in all orientations.

63. The respirator of claim 61, wherein the curvature of the cantilevered valve flap comprises a constant curvature.

64. The respirator of claim 61, wherein the curvature of the cantilevered valve flap varies from the first end to the second end.

65. The respirator of claim 61, wherein the opening is generally planar such that the curvature of the cantilevered valve flap attached to the face mask over the opening is flattened when the cantilevered valve flap seals the opening in the face mask.

66. The respirator of claim 61, wherein the face mask is formed of a filtering material.

67. The respirator of claim 61, wherein the unidirectional valve is an exhalation valve.

68. The respirator of claim 61, wherein the unidirectional valve is an inhalation valve.

69. The respirator of claim 61, wherein the cantilevered valve flap further comprises a top surface, a bottom surface, and at least one support element extending from the top surface of the cantilevered valve flap, wherein the at least one support element provides the curvature in the cantilevered valve flap that is at least partially flattened when the cantilevered valve flap seals the opening.

71. The respirator of claim 61, wherein the cantilevered valve flap further comprises a top surface, a bottom surface, wherein the cantilevered valve flap further comprises a plurality of support elements extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support element, and wherein the plurality of support elements provide the curvature in the cantilevered valve flap that is at least partially flattened when the cantilevered valve flap seals the valve opening.

EVIDENCE APPENDIX

Serial No.: 09/888,943

Docket No.: 56842US002

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1. Lübeck (DE 1213249) (translation) (entered in the record by citation within the Non-final Office Action of 8 February 2007).
 2. Japuntich et al. (U.S. Patent No. 5,509,436) (entered in the record by citation within the Non-final Office Action 13 August 2002).
 3. Advisory Action of 6 August 2008.
 4. Final Office Action of 27 June 2008.
 5. Non-final Office Action of 29 November 2007.
 6. Response to Non-final Office Action of 28 March 2008.
 7. Response to Final Office Action of 9 July 2008.
 8. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (Bd. Pat. App. & Inter. 1990).
 9. *In re Rijckaert*, 9 F.3d 1531, 28 U.S.P.Q.2d 1955 (Fed. Cir. 1993).
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 13. 35 U.S.C. §102(b).
 14. 35 U.S.C. §103(a).
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 19. M.P.E.P. §2112(IV), p. 2100-47, 8th Ed., Rev. 6, (Sept. 2007).
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Open Laying/ Disclosure Document

1 213 249

Valve for respiratory protection equipment, respiratory protection masks, or similar devices.

Applicant: Drägerwerk, Heinr. & Bernh. Dräger, Lübeck, Moislinger Allee 53/55

Respiratory protection equipment, respiratory protection masks, or similar devices are equipped with valves of different varieties that are utilized as control valves, pressure relief valves, check valves, or similar.

It is known that said valves can be designed, for example, to be created as so called mica disc valves, or also as rubber disc valves that possess a closing component that consists of a mica, respectively rubber disc. Mica disc valves are rather involved in their construction because of the fact that the mica disc has to be guided in a specifically designed cage, and that it has to be loaded with a spring in the direction of its closing operation. Furthermore, the installation of the cage that is containing the disc requires rather much space, which leads to the fact that the air passage channels on the one side of the mica disc possess a larger diameter than the ones on the other side. This is also required to achieve an as low as possible flow resistance herewith.

However, I could imagine utilizing different materials than mica, but that will not change any of the described disadvantages.

Furthermore, also known are exhaling valves for respiratory protection masks that consist of elastic, pliable materials, such as rubber, plastic substances, or similar, with a centrally attached valve closing body that is designed in the way of a truncated cone mantle between its exterior edge and the exterior edge of its strengthened center section. With such a valve, the closing force with the closed valve is generated by means of deformation that is applied to the closing body if it is lying against the valve seat. Upon the passage of

air, the closing body lifts up at its edges and away from the valve seat, and it gets deformed into an almost flat surface. Valves of this kind can also be designed in such a manner that the truncated cone mantle that creates the closing body is separated into concentric rings, step like, and offset to each other. Said rings of the truncated cone mantle can approximately possess a sinusoidal shaped cross section. Finally, it is also known to reduce the thickness of the valve closing body of such valves between the exterior edge of the strengthened center section and the exterior edge of the disc. With all of these valves, the enclosure gets a larger diameter on the outlet side than the one that correlates with the valve closing body to achieve a lower flow resistance.

Furthermore known is an inhaling valve for respiratory protection masks that possesses a valve seat that is created by the body wall of said mask, and that is covered by means of a rubber disc creates the closing body. Herewith, said rubber disc is attached with both of it's sides, and about along it's center axis, to the wall of said mask. With other execution examples of said valve, the valve opening in the mask wall is enforced by a web, to which the rubber disc is attached at one point. Said valve closing bodies are not exposed to any tension if the valve is closed, and they can open into arbitrary directions.

Finally, there is an inhaling valve for full head masks known with which the body of the mask is created into a valve seat at the point at which the valve is supposed to be located, and the closing body that is designed as a membrane is partially glued or vulcanized to the mask body. Herewith, it is possible that said membrane could be glued to said mask body in an uninterrupted manner for the largest part of its circumference, in such a manner that a pocket will be created from which the exhaled air can exit. Herewith, it is possible to achieve a certain flow direction for the exiting air; however, it is not possible to create any predetermined closing force with said closing body.

The invention is concerned with a valve for respiratory protection equipment, respiratory protection masks, or similar devices that possesses a disc shaped, bendable valve closing body that is attached to the respiratory protection apparatus, the respiratory protection mask or similar along a straight line and at several points. The scope of the invention is to improve a valve of such kind in such a manner that the closing body on the one side lays against the valve seat with a certain closing force, and on the other-side that it opens into a determined direction. According to the invention, the solution of this scope consists of the fact that the valve closing is equipped with one or several ribs at the opposite side of the valve seat, and of which at least one crosses the attachment line of the valve closing body in a rectangular manner. A valve closing body that is produced following the invention possesses the advantage that the valve closing body flaps open in only a predetermined direction, and that a certain force is required to open said valve closing body. Furthermore, there are no modifications required to the simple design of the valve seat.

Further characteristics of the invention are subject to the sub-claims.

Execution examples of the invention will be explained with the support of the drawing. Displayed is in:

Fig. 1 a cross sectional cut through he first execution example,

Fig. 2 the top view to Fig. 1,

Fig. 3, the valve that is installed into a bent tube section,

Fig. 4 the view in the direction of the arrow A in Fig. 3,

Fig. 5 an isometric display of the valve closing body following the Figs. 1 and 2,

Fig. 6 the closing body following Fig. 5 in it's open condition, and

Fig. 7 a further execution version, also in an isometric display manner.

With the displays following the Figs. 1 through 6, the valve closing body 1 is equipped with a rib 2 that proceeds across the bending axis C-C. Said rib is created to resemble a bridge 3 in the area of the bending axis, which means, it is not in connection with the valve closing body 1 in the area of the bending axis C-C. However, there remains rather a free space between the closing body and said rib 2. Beyond the bending axis C-C, the rib 2 is split-up into 3 ribs 4, 5, and 6 that are lying across the surface of the body in a flabelliform manner. This results in a strengthening of the valve closing body in this area.

On it's side that is directed toward the valve seat, the valve closing body contains pegs 7 that are each inserted into a bore 8 of the valve closing body carrier 9 that, in turn, is connected to the valve carrier 10. Said carrier is equipped with the valve seat 11.

According to the Figs. 3 and 4, the valve closing body 1 is equipped with two pegs 12 and 13 that engage with the relevant counter pieces of a web 14 that is connected to the valve carrier 10, and that thus holds the valve closing body 1. Because of increased resistance strength, the web 14 is equipped with a rib 14a that is positioned in the center across from it's longitudinal axis. As it can be seen from the Figs. 3 and 6, the bridge 3 of the rib 2 bends over to the side upon opening the valve. This sideward bending over causes that the material of the rib does not need to be compressed via the bending axis C-C, which in turn would result in an increased resistance during the bending of the valve closing body 1. It is achieved by means of said bridge-like creation of said ribs that the opening resistance will not be increased any more, or that it will not be increased excessively and continuously, which means, that a too strong increase of the flow resistance will be avoided herewith. The valve closing body achieves it's required closing force by means of the rib 2.

As it is displayed in the Figs. 3 and 4, the exhaling enclosure 18 can be kept quite a bit smaller because the valve closing body 1 opens only into the displayed direction. The manner, in which said valve closing body opens could be adapted to the relevant conditions by means of the selection of the attachment line. Because of the eccentric attachment of the valve closing body following Fig. 3, the air is directed immediately into the tube elbow.

Fig. 7 displays a different constructional execution version with which the valve closing body 19 is equipped with two ribs 20 that are designed in a bridge like fashion in the areas of the bending axis D-D that is displayed in the drawing by means of dotted lines. A pin 22 is utilized for attaching the closing body. Said pin is put through the one end of the ribs 20, and it is attached with both of its sides to the valve carrier 23. The pin 23 will not create the pivoting axis, rather the two bridges 21 will bend out during the opening process of said valve; this means, the bending axis D-D is rather placed in front of the pin 22. With very high flow rates, also the smaller segment 24, respectively, 25 of the valve closing body 1, respectively, 9 will be lifted away from the valve seats with both types of valves.

Patent Claims

1. A valve for respiratory protection equipment, respiratory protection mask, or similar devices that is equipped with a disc shaped, bendable valve closing body that is attached along a straight line at several points in the respiratory protection equipment, the respiratory protection mask, or similar devices, characterized in such a way that the valve closing body (1, respectively, 19) is equipped with one or several ribs (2, 4, 5, and 6, respectively, 14a, respectively, 20) on its side that is in the opposing position to the valve seat, and with which at least one of said ribs crosses the attachment line of the valve closing body (1, respectively, 19) in a rectangular angle to said line.
2. A valve according to claim 1, characterized in such a way that the rib (2), or the ribs (20) are designed to represent bridge like structures (3) at least in the area of the bending axis (C-C, respectively, D-D) of the valve closing body (1, respectively, 19).
3. A valve according to the claims 1, or 2, characterized in such a way that the rib, or the ribs are arranged and designed in such a manner, and that the attachment line of the valve closing body proceeds in such a way that the bending axis proceeds through it's center.
4. A valve according to one of the claims 1 through 3, characterized in such a way that the rib (2), or the ribs proceed at least with one of their ends all the way to the edge of the valve closing body (1).
5. A valve according to claim 4, characterized in such a way that the extensions that proceed to the edge consists of several, flabelliform distributed and positioned ribs (4, 5, and 6).
6. A valve according tone of the claims 1 through 5, characterized in such a way that the valve closing body (1) is equipped with several pegs (7, respectively, 12, and 13) along its bending axis (C-C), and on the side that is opposing the side that contains the ribs (2, 4, 5, and 6, respectively, 14a), and that said pegs (7, respectively, 12, and 13) are utilized for it's attachment to the valve closing body carrier (9).
7. A valve according to one of the claims 1 through 5, characterized in such a way that the valve closing body (19) is connected to a pin like holder in a manner that

allows for pivoting motions, and with which said pin shaped holder runs through or above the rib or ribs (20), and with which said pin shaped holder is attached at one or both of its sides to the valve carrier (23) outside of the valve seat.

Printed documents that were considered herewith:

German Patent Documents No. 460 840, 1 027 518, 1 055 969;

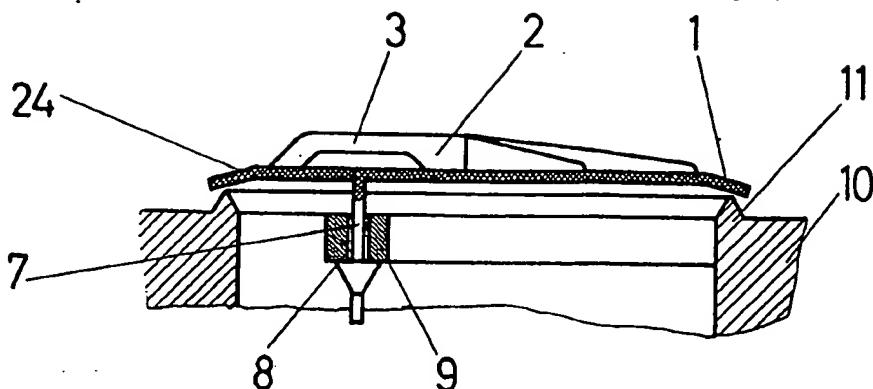
Swiss Patent Document: No. 200 482;

US Patent Document No. 2 895 472.

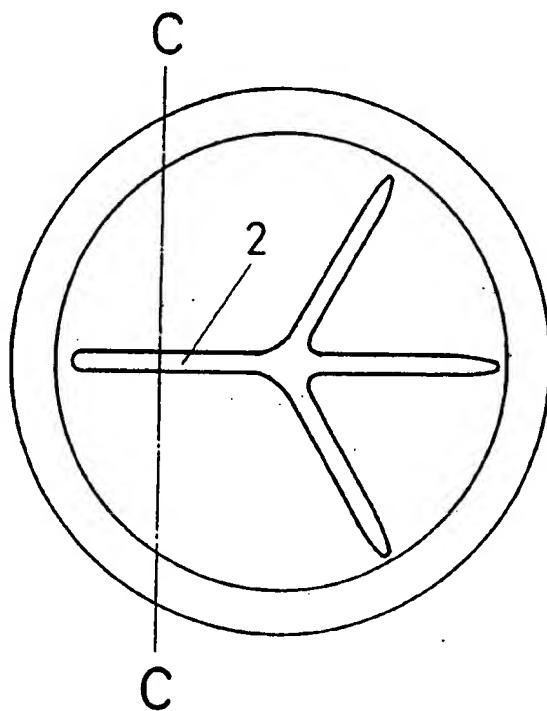
Herewith 1 Sheet of Drawings

Translated by:
Dietmar Schlei
(715) 386-5779
(651) 736-2057

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Auslegetag: 24. März 1966

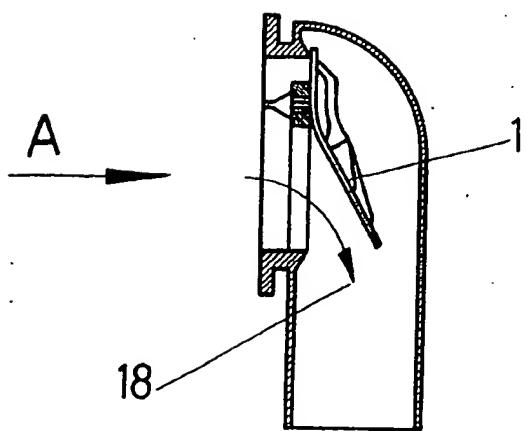


*Fig.
Abb. 1*

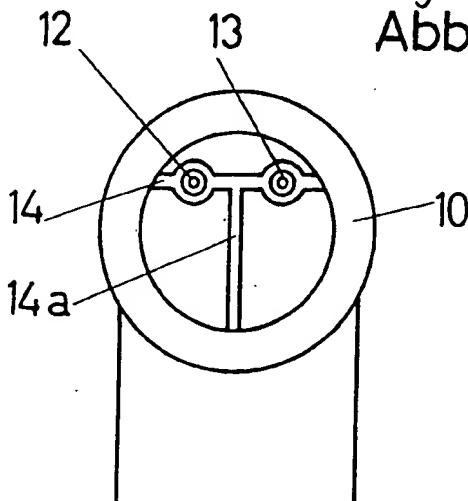


*Fig.
Abb. 2*

*Fig.
Abb. 3*



*Fig.
Abb. 4*



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Fig.
Abb.5

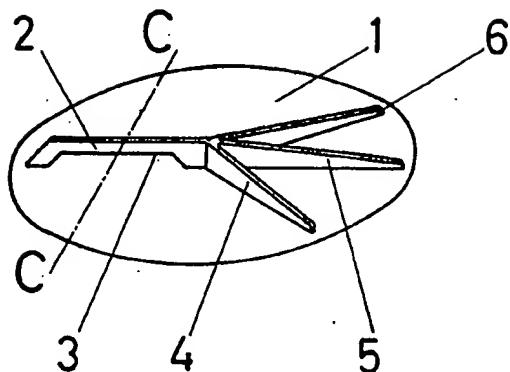


Fig.
Abb.6

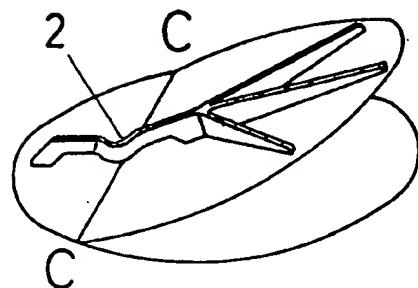
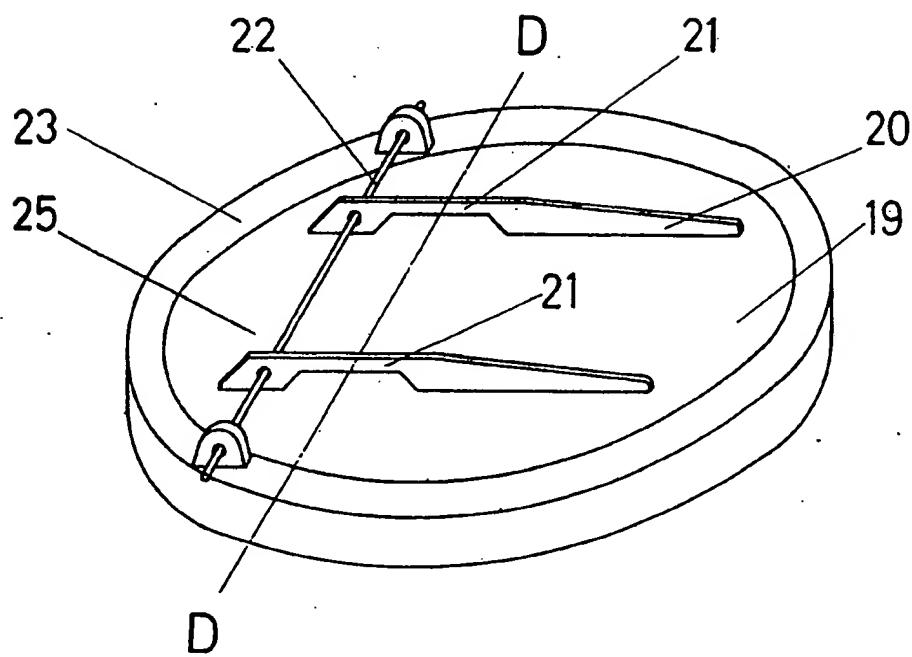


Fig.
Abb.7





AUSLEGESCHRIFT

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Anmeldetag: 29. Mai 1962
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1

Atemschutzgeräte, Atemschutzmasken u. dgl. sind mit Ventilen unterschiedlicher Art ausgerüstet, die als Steuerventile, Überdruckventile, Rückschlagventile od. dgl. dienen.

Es ist bekannt, diese Ventile z. B. als sogenannte Glimmerventile oder auch als Gummischeibenventile auszubilden, deren Verschlußkörper aus einer Glimmer- bzw. Gummischeibe besteht. Glimmerventile sind aufwendig und kompliziert in ihrem Aufbau, da die Glimmerscheibe in einem besonders gestalteten Käfig geführt und in Schließrichtung mit einer Feder belastet sein muß. Außerdem fordert der Einbau des die Scheibe haltenden Käfigs verhältnismäßig viel Raum, so daß die Luftführungskanäle auf der einen Seite der Glimmerscheibe einen größeren Durchmesser haben als auf der anderen Seite. Dies ist auch notwendig, um einen möglichst geringen Strömungswiderstand zu erhalten.

Es ist zwar denkbar, an Stelle des Glimmers andere Materialien zu verwenden, doch wird dadurch an den beschriebenen Nachteilen nichts geändert.

Weiter sind Ausatemventile für Atemschutzmasken mit aus elastisch nachgiebigem Stoff, wie Gummi, Kunststoff o. dgl., bestehendem und mittig befestigtem Ventilverschlußkörper bekannt, der zwischen seinem Außenrand und dem Außenrand seines verstärkten Mittelteils als Kegelstumpfmantel ausgebildet ist. Bei einem solchen Ventil wird die Schließkraft bei geschlossenem Ventil durch die Verformung erzeugt, welche der Verschlußkörper erfährt, wenn er an dem Ventilsitz anliegt. Bei Luftpumpe hebt sich der Verschlußkörper an seinem Rand von dem Ventilsitz ab und wird zu einer nahezu ebenen Fläche verformt. Dabei wird die Rückstellkraft des Verschlußkörpers kleiner. Derartige Ventile können auch so ausgebildet sein, daß der den Verschlußkörper bildende Kegelstumpfmantel in konzentrische, stufenförmig gegeneinander versetzte Ringe aufgelöst ist. Die Ringe des Kegelstumpfmantels können einen etwa sinusförmigen Querschnitt haben. Schließlich ist es bekannt, die Dicke des Ventilverschlußkörpers derartiger Ventile zwischen dem Außenrand des verstärkten Mittelteils und dem Außenrand der Scheibe abnehmen zu lassen. Bei allen diesen Ventilen erhält das Gehäuse auf der Abströmseite einen größeren lichten Durchmesser als dem Ventilverschlußkörper entspricht, um einen geringen Strömungswiderstand zu erreichen.

Es ist ferner ein Einatemventil für Atemschutzmasken bekannt, dessen Ventilsitz von der Maskenkörperwand gebildet und durch eine den Verschlußkörper bildende Gummischeibe abgedeckt ist, die

Ventil für Atemschutzgeräte, Atemschutzmasken u. dgl.

Anmelder:
 Drägerwerk, Heinr. & Bernh. Dräger,
 Lübeck, Moislinger Allee 53/55

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etwa längs ihrer Mittellinie beiderseitig an der Maskenwand befestigt ist. Bei einer anderen Ausführungsform dieses Ventils ist die Ventilöffnung in der Maskenwand von einem Steg durchsetzt, an dem die Gummischeibe in einem Punkt befestigt ist. Diese Ventilverschlußkörper stehen bei geschlossenem Ventil überhaupt nicht unter Spannung und öffnen sich in beliebiger Richtung.

Schließlich ist noch ein Ausatemventil für Haubenmasken bekannt, bei dem der Maskenkörper an der für das Ventil vorgesehenen Stelle zu einem Ventilsitz geformt und der als Membran ausgebildete Verschlußkörper an dem Maskenkörper stellenweise angeklebt oder an vulkanisiert ist. Die Membran kann ununterbrochen am größten Teil ihres Umfangs am Maskenkörper angeklebt sein, so daß eine Tasche gebildet ist, aus der die abströmende Luft hinaustreten kann. Dadurch wird zwar eine bestimmte Strömungsrichtung für die durchtretende Luft geschaffen, jedoch kann in dem Verschlußkörper keine festgelegte Schließkraft erzeugt werden.

Die Erfindung betrifft ein Ventil für Atemschutzgeräte, Atemschutzmasken u. dgl. mit einem scheibenförmigen, biegsamen Ventilverschlußkörper, der längs einer geraden Linie in mehreren Punkten an dem Atemschutzgerät, der Atemschutzmaske u. dgl. befestigt ist. Der Erfindung liegt die Aufgabe zugrunde, ein Ventil dieser Art so zu verbessern, daß der Verschlußkörper einerseits mit einer bestimmten Schließkraft dem Ventilsitz anliegt und andererseits sich in einer festgelegten Richtung öffnet. Die Lösung dieser Aufgabe besteht nach der Erfindung darin, daß der Ventilverschlußkörper an seiner dem Ventilsitz entgegengesetzten Seite mit einer oder mehreren Rippen versehen ist, von denen wenigstens eine die Befestigungslinie des Ventilverschlußkörpers unter einem zu dieser rechten Winkel kreuzt. Ein Ventil nach der Erfindung hat den Vorteil, daß der Ventilverschlußkörper nur in einer festgelegten Richtung hochklappt und zum Öffnen eine bestimmte Kraft erforderlich ist. Weiter braucht an dem einfachen Aufbau des ringförmigen Ventilsitzes nichts geändert zu werden.

Weitere Merkmale der Erfindung sind Gegenstand der Unteransprüche.

Ausführungsbeispiele der Erfindung werden an Hand der Zeichnung erläutert. Es zeigt

A b b. 1 einen Querschnitt durch das erste Ausführungsbeispiel,

A b b. 2 die Draufsicht zu A b b. 1,

A b b. 3 das in einen Rohrkümmel eingebaute Ventil,

A b b. 4 die Ansicht in Richtung des Pfeiles A in A b b. 3,

A b b. 5 eine räumliche Darstellung des Ventilverschlußkörpers nach A b b. 1 und 2,

A b b. 6 den Verschlußkörper nach A b b. 5 in aufgeklapptem Zustand und

A b b. 7 eine weitere Ausbildungsform, ebenfalls in räumlicher Darstellung.

Bei der Ausbildungsform nach A b b. 1 bis 6 ist der Ventilverschlußkörper 1 mit einer Rippe 2 versehen, die quer zur Biegeachse C-C verläuft. Im Bereich der Biegeachse ist die Rippe als Brücke 3 ausgebildet, d. h., daß sie im Bereich der Biegeachse C-C nicht mit dem Ventilverschlußkörper 1 verbunden ist, sondern daß ein Zwischenraum zwischen dem Verschlußkörper und der Rippe 2 frei bleibt. Die Rippe 2 ist jenseits der Biegeachse C-C in drei fächerartig angeordnete Rippen 4, 5 und 6 aufgegliedert, wodurch eine Verstärkung des Ventilverschlußkörpers in diesem Bereich erreicht wird.

Der Ventilverschlußkörper trägt auf seiner dem Ventilsitz zugewendeten Seite Zapfen 7, die je in eine Bohrung 8 des Ventilverschlußkörperträgers 9 eingesteckt sind, der seinerseits mit dem Ventilträger 10 verbunden ist. Dieser ist mit dem Ventilsitz 11 versehen.

Nach A b b. 3 und 4 ist der Ventilverschlußkörper 1 mit zwei Zapfen 12 und 13 versehen, die in entsprechende Gegenstücke eines Steges 14 greifen, der am Ventilträger 10 befestigt ist und damit den Ventilverschlußkörper 1 hält. Der Steg 14 ist im Interesse der Widerstandsfähigkeit mit einer quer zu seiner Längsachse mittig angeordneten Rippe 14a versehen. Wie A b b. 3 und 6 zeigen, biegt sich bei geöffnetem Ventil die Brücke 3 der Rippe 2 seitlich aus. Dieses seitliche Ausknicken hat zur Folge, daß über der Biegeachse C-C das Material der Rippe nicht gestaucht werden muß, wodurch sich ein steigender Widerstand beim Biegen des Ventilverschlußkörpers 1 ergeben würde. Durch die brückenartige Ausbildung der Rippe wird erreicht, daß nach dem Öffnen des Ventils der Öffnungswiderstand nicht weiter oder nicht übermäßig weiter ansteigt, also ein zu starkes Ansteigen des Strömungswiderstandes vermieden wird. Der Ventilverschlußkörper erhält durch die Rippe 2 die nötige Schließkraft.

Wie A b b. 3 und 4 zeigen, kann das Abströmgehäuse 18 wesentlich kleiner gehalten werden, da der Ventilverschlußkörper 1 sich nur in der dargestellten Richtung öffnet. Die Art, wie sich der Verschlußkörper öffnet, kann durch die Wahl der Befestigungslinie den jeweiligen Verhältnissen angepaßt werden. Die Luft wird infolge der exzentrischen Befestigung des Ventilverschlußkörpers gemäß A b b. 3 sogleich in Richtung des Rohrkümmers gelenkt.

A b b. 7 zeigt eine andere Bauform, bei der der Ventilverschlußkörper 19 mit zwei Rippen 20 versehen ist, die im Bereich der gestrichelt gezeichneten Biegeachse D-D brückenartig ausgebildet sind. Zum

Befestigen des Verschlußkörpers dient ein Stift 22, der durch das eine Ende der Rippen 20 gesteckt und beiderseitig am Ventilträger 23 gehalten ist. Der Stift 22 bildet nicht die Schwenkachse, vielmehr knicken 5 beim Öffnen des Ventils die beiden Brücken 21 ein; die Biegeachse D-D liegt also vor dem Stift 22. Bei beiden Ventilen wird bei sehr hohen Strömungsgeschwindigkeiten auch das kleinere Segment 24 bzw. 25 des Ventilverschlußkörpers 1 bzw. 19 vom Ventilsitz abgehoben.

Patentansprüche:

1. Ventil für Atemschutzgeräte, Atemschutzmasken u. dgl. mit einem scheibenförmigen, biegsamen Ventilverschlußkörper, der längs einer geraden Linie in mehreren Punkten in dem Atemschutzgerät, der Atemschutzmaske u. dgl. befestigt ist, dadurch gekennzeichnet, daß der Ventilverschlußkörper (1 bzw. 19) an seiner dem Ventilsitz entgegengesetzten Seite mit einer oder mehreren Rippen (2, 4, 5 und 6 bzw. 14a bzw. 20) versehen ist, von denen wenigstens eine die Befestigungslinie des Ventilverschlußkörpers (1 bzw. 19) unter einem zu dieser rechten Winkel kreuzt.

2. Ventil nach Anspruch 1, dadurch gekennzeichnet, daß die Rippe (2) oder die Rippen (20) zumindest im Bereich der Biegeachse (C-C bzw. D-D) des Ventilverschlußkörpers (1 bzw. 19) als Brücken (3) ausgebildet sind.

3. Ventil nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Rippe oder Rippen derart angeordnet und ausgebildet sind und die Befestigungslinie des Ventilverschlußkörpers derart verläuft, daß die Biegeachse des Ventilverschlußkörpers durch dessen Mitte verläuft.

4. Ventil nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Rippe (2) oder die Rippen wenigstens an ihrem einen Ende bis zum Rand des Ventilverschlußkörpers (1) geführt sind.

5. Ventil nach Anspruch 4, dadurch gekennzeichnet, daß die bis zum Rand geführten Verlängerungen aus mehreren vorzugsweise fächerartig angeordneten Rippen (4, 5 und 6) bestehen.

6. Ventil nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der Ventilverschlußkörper (1) längs der Biegeachse (C-C) auf der den Rippen (2, 4, 5 und 6 bzw. 14a) entgegengesetzten Seite mit mehreren Zapfen (7 bzw. 12 und 13) zum Befestigen an dem Ventilverschlußkörperträger (9) versehen ist.

7. Ventil nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der Ventilverschlußkörper (19) an einem über oder durch die Rippe oder Rippen (20) geführten stabförmigen Halter schwenkbar angeschlossen ist, der ein- oder beiderseitig außerhalb des Ventilsitzes am Ventilträger (23) befestigt ist.

In Betracht gezogene Druckschriften:
Deutsche Patentschriften Nr. 460 840, 1 027 518,
1 055 969;
schweizerische Patentschrift Nr. 200 482;
USA.-Patentschrift Nr. 2 895 472.

Hierzu 1 Blatt Zeichnungen

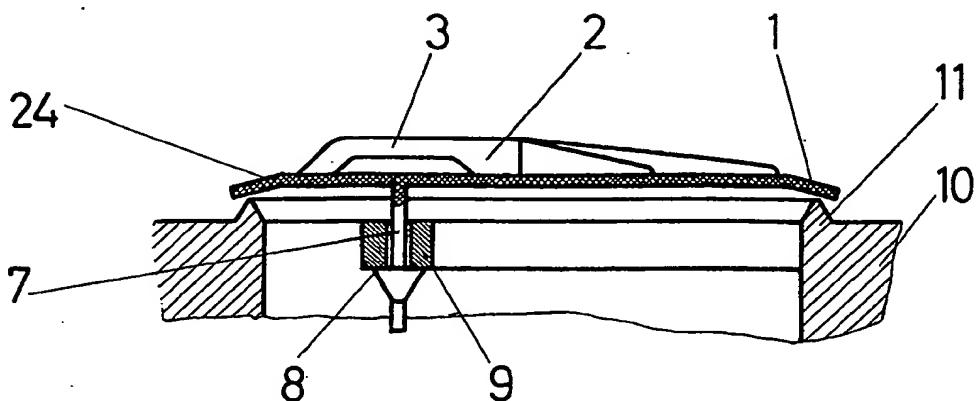


Abb.1

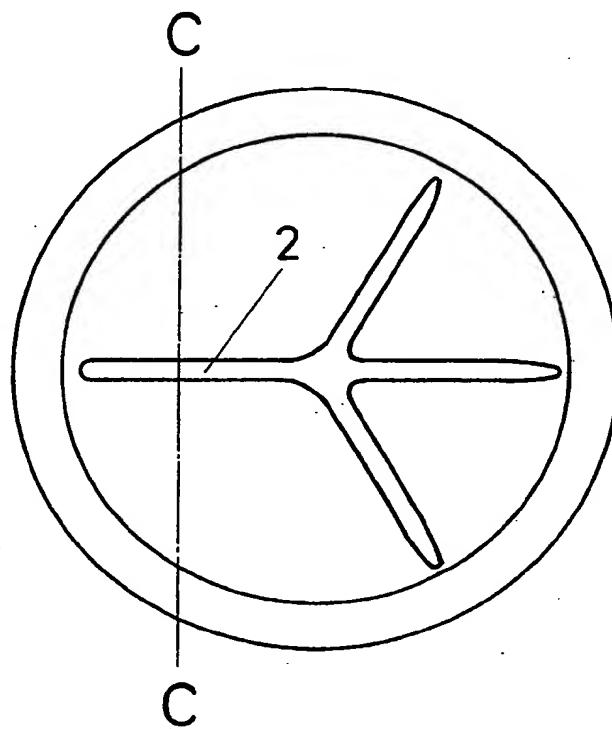


Abb.2

Abb.3

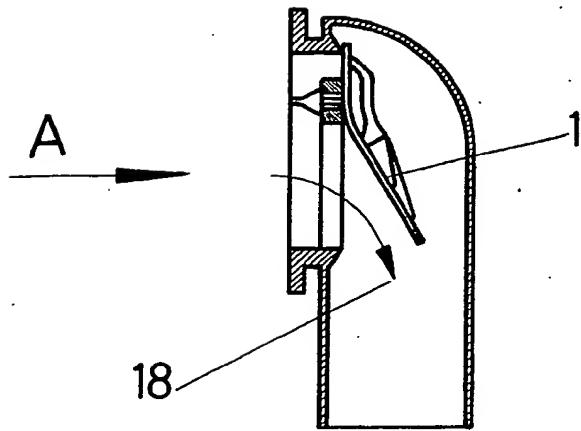


Abb.4

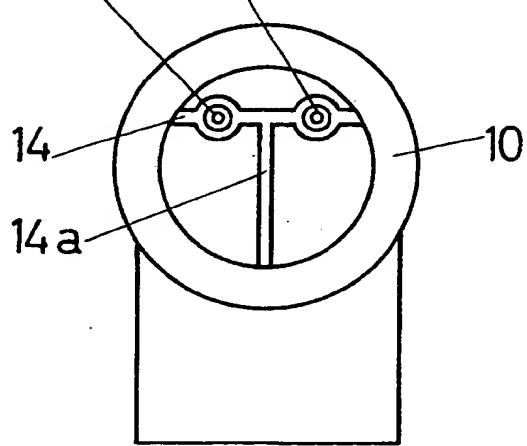


Abb.5

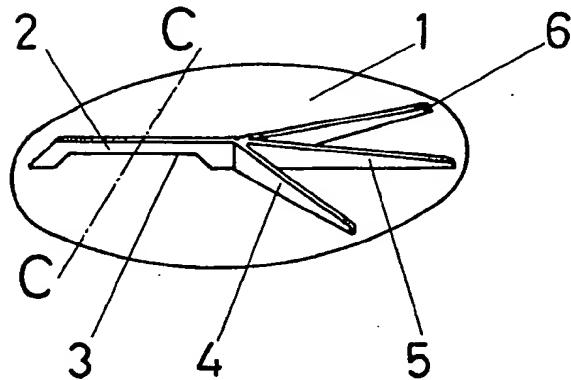


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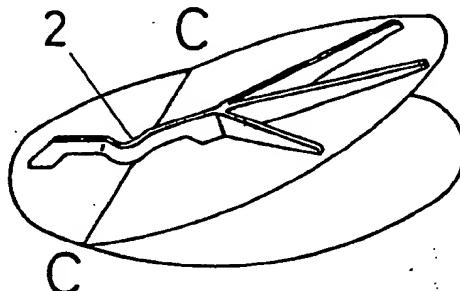
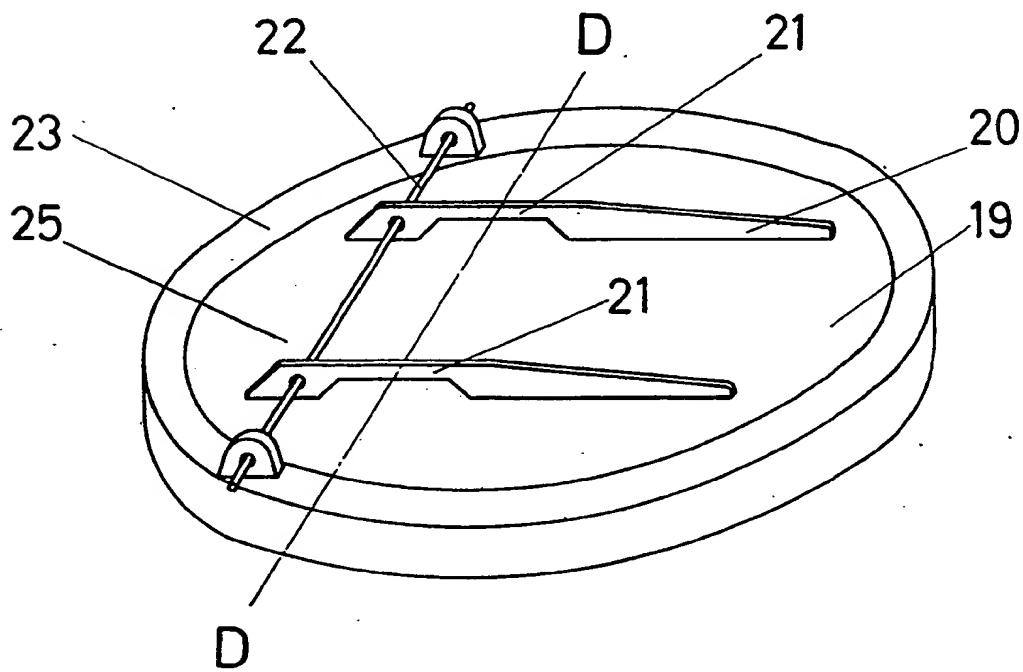


Abb.7





US005509436A

United States Patent [19]

Japuntich et al.

[11] Patent Number: 5,509,436

[45] Date of Patent: Apr. 23, 1996

[54] UNIDIRECTIONAL FLUID VALVE

[75] Inventors: Daniel A. Japuntich, St. Paul; Vaughn B. Grannis, Inver Grove Heights; Harold J. Seppala, St. Paul; Anthony B. Ferguson, Woodbury, all of Minn.

[73] Assignee: Minnesota Mining and Manufacturing Company, St. Paul, Minn.

[21] Appl. No.: 448,088

[22] Filed: May 23, 1995

Related U.S. Application Data

[62] Division of Ser. No. 240,877, May 11, 1994, which is a division of Ser. No. 981,244, Nov. 25, 1992, Pat. No. 5,325,892, which is a continuation-in-part of Ser. No. 891,289, May 29, 1992, abandoned.

[51] Int. Cl.⁶ F16K 15/16

[52] U.S. Cl. 137/15

[58] Field of Search 137/15, 855-858

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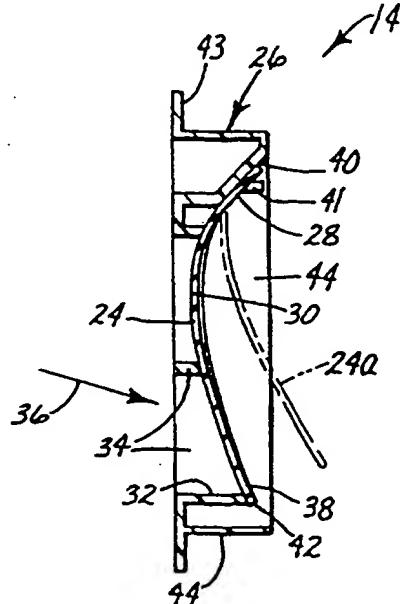
Primary Examiner—Robert G. Nilson

Attorney, Agent, or Firm—Gary L. Griswold; Walter N. Kirn; Karl G. Hanson

[57] ABSTRACT

An exhalation valve 14 for a filtering face mask 10 has a flexible flap 24 that makes contact with a curved seal ridge 30 of a valve seat 26 when the valve 14 is in the closed position. The curvature of the seal ridge 30 corresponds to a deformation curve exhibited by the flexible flap 24 when secured as a cantilever at one end and exposed at its free portion to a uniform force and/or a force of at least the weight of the free portion of the flexible flap. A seal ridge curvature corresponding to a flexible flap exposed to uniform force allows the flexible flap 24 to exert a generally uniform pressure on the seal ridge to provide a good seal. A seal ridge curvature corresponding to a flexible flap exposed to a force of at least the weight of the flap's free portion allows the flexible flap 24 to be held in an abutting relationship to the seal ridge 30 under any static orientation by a minimum amount of force, thereby providing a face mask 10 with an extraordinary low pressure drop during an exhalation.

16 Claims, 2 Drawing Sheets



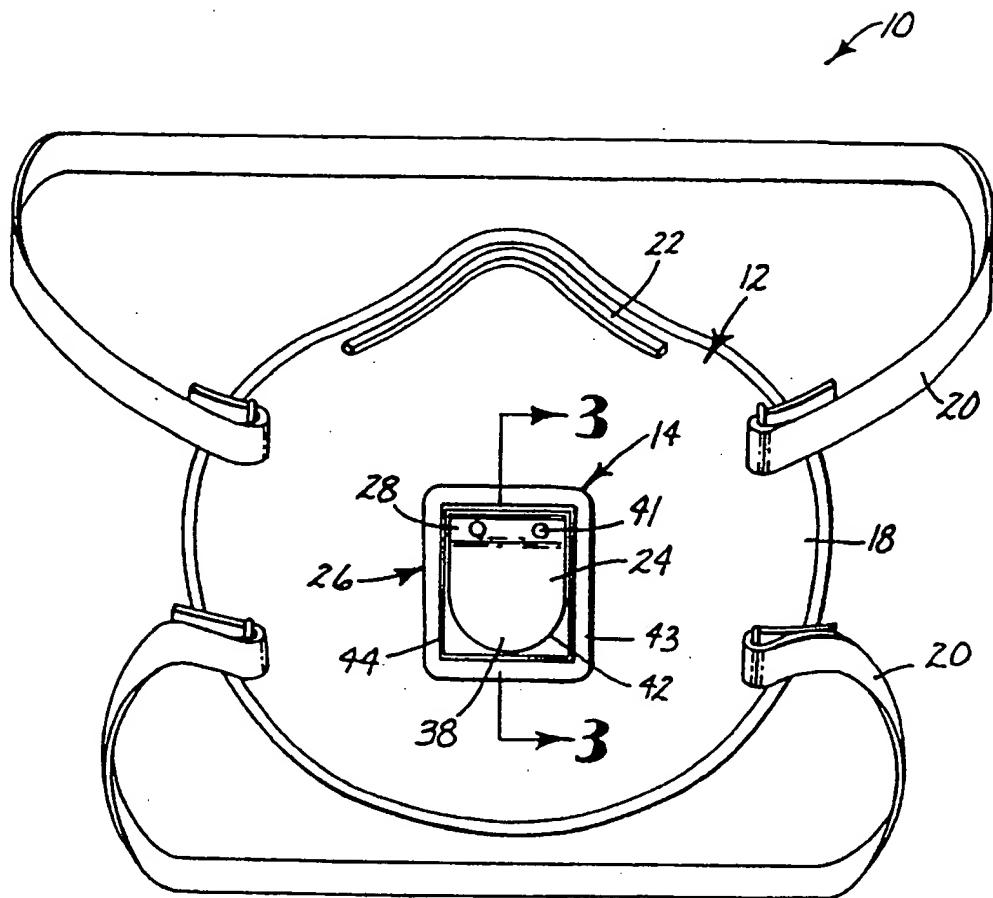


Fig. 1

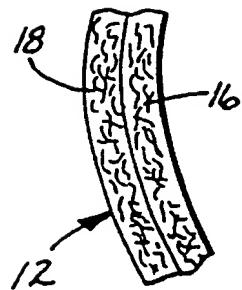


Fig. 2

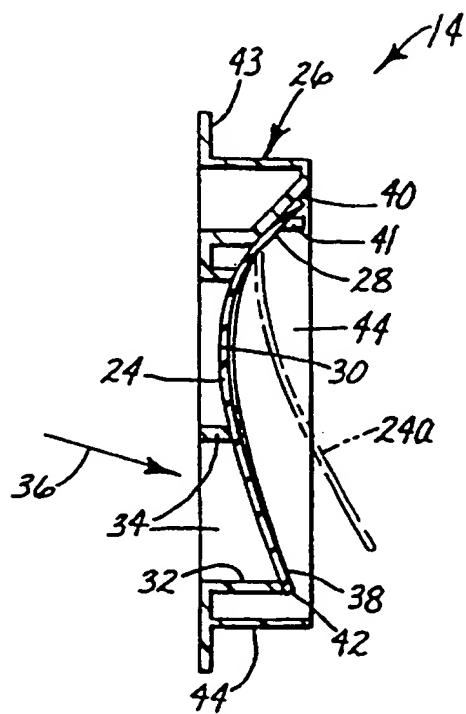


Fig. 3

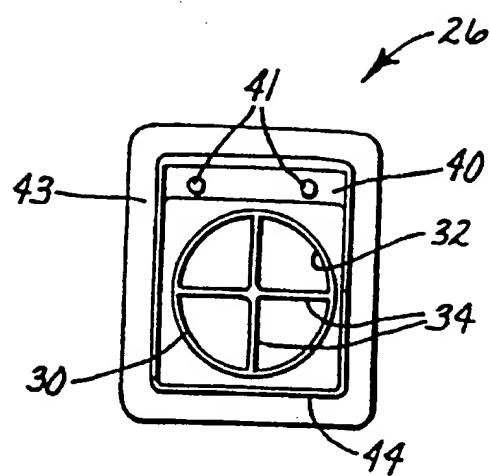


Fig. 4

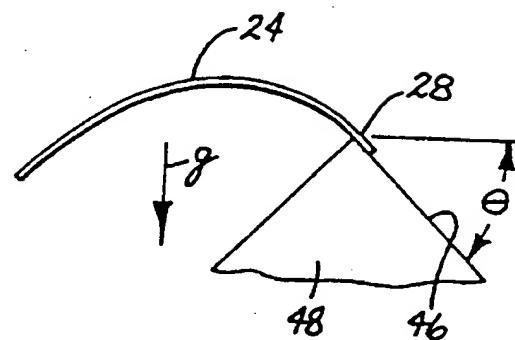


Fig. 5

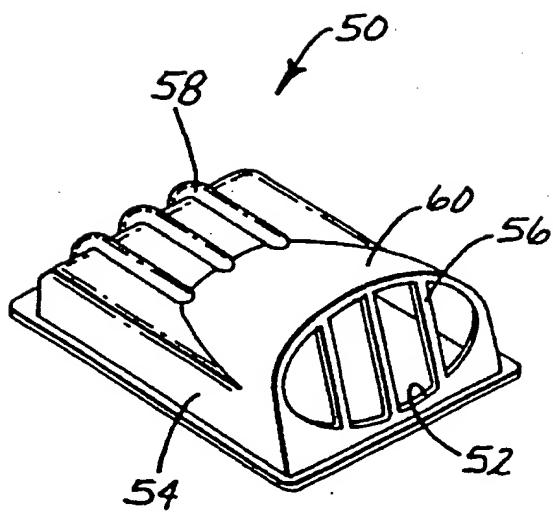


Fig. 6

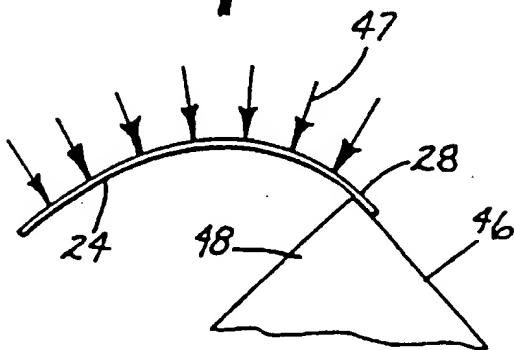


Fig. 7

UNIDIRECTIONAL FLUID VALVE

This is a division of U.S. patent application Ser. No. 08/240,877 filed May 11, 1994, which is a division of U.S. patent application Ser. No. 07/981,244 filed Nov. 25, 1992, now U.S. Pat. No. 5,325,892, which is a continuation-in-part of U.S. patent application Ser. No. 07/891,289 filed May 29, 1992, now abandoned. The disclosures of these applications are incorporated here by reference.

TECHNICAL FIELD

This invention pertains to (i) a unidirectional fluid valve that can be used as an exhalation valve for a filtering face mask, (ii) a filtering face mask that employs an exhalation valve, and (iii) a method of making a unidirectional fluid valve.

BACKGROUND OF THE INVENTION

Exhalation valves have been used on filtering face masks for many years and have been disclosed in, for example, U.S. Pat. Nos. 4,981,134, 4,974,586, 4,958,633, 4,934,362, 4,838,262, 4,630,604, 4,414,973, and 2,999,498. U.S. Pat. No. 4,934,362 (the '362 patent), in particular, discloses a unidirectional exhalation valve that has a flexible flap secured to a valve seat, where the valve seat has a rounded seal ridge with a parabolic profile. The elastomeric flap is secured to the valve seat at the apex of the parabolic curve, and rests on the rounded seal ridge when the valve is in a closed position. When a wearer of a face mask exhales, the exhaled air lifts the free end of the flexible flap off the seal ridge, thereby allowing the exhaled air to be displaced from the interior of the face mask. The '362 patent discloses that an exhalation valve of this construction provides a significantly lower pressure drop for a filtering face mask.

SUMMARY OF THE INVENTION

In a first aspect, the present invention provides a unidirectional fluid valve that comprises a flexible flap having a first portion and a second portion, the first portion being attached to a valve seat, the valve seat having an orifice and a seal ridge that has a concave curvature when viewed from a side elevation, the flexible flap making contact with the concave curvature of the seal ridge when a fluid is not passing through the orifice, the second portion of the flexible flap being free to be lifted from the seal ridge when a fluid is passing through the orifice, wherein the concave curvature of the seal ridge corresponds to a deformation curve exhibited by the second portion of the flexible flap when exposed to a uniform force, a force having a magnitude equal to a mass of the second portion of the flexible flap multiplied by at least one gravitational unit of acceleration, or a combination thereof.

In a second aspect, the present invention provides a filtering face mask that comprises:

- (a) a mask body adapted to fit over the nose and mouth of a person; and
- (b) an exhalation valve attached to the mask body, which exhalation valve comprises:
 - (1) a valve seat having (i) an orifice through which a fluid can pass, and (ii) a seal ridge circumscribing the orifice and having a concave curvature when viewed from a side elevation, the apex of the concave curvature of the seal ridge being located upstream to

fluid flow through the orifice relative to outer extremities of the concave curvature; and

(2) a flexible flap having a first and second portions, the first portion being attached to the valve seat outside a region encompassed by the orifice, and the second portion assuming the concave curvature of the seal ridge when the valve is in a closed position and being free to be lifted from the seal ridge when a fluid is passing through the orifice.

10 In a third aspect, the present invention provides a filtering face mask that comprises:

(a) a mask body that has a shape adapted to fit over the nose and mouth of a person, the mask body having a filter media for removing contaminants from a fluid that passes through the mask body, there being an opening in the mask body that permits a fluid to exit the mask body without passing through the filter media, the opening being positioned on the mask body such that the opening is substantially directly in front of a wearer's mouth when the filtering face mask is placed on a wearer's face over the nose and mouth; and

(b) an exhalation valve attached to the mask body at the location of the opening, the exhalation valve having a flexible flap and a valve seat that includes an orifice and a seal ridge, the flexible flap being attached to the valve seat at a first end and resting upon the seal ridge when the exhalation valve is in a closed position, the flexible flap having a second free-end that is lifted from the seal ridge when a fluid is passing through the exhalation valve;

wherein, the fluid-permeable face mask can demonstrate a negative pressure drop when air is passed into the filtering face mask with a velocity of at least 0.8 m/s under a normal exhalation test.

In a fourth aspect, the present invention provides a method of making a unidirectional fluid valve, which comprises:

(a) providing a valve seat that has an orifice circumscribed by a seal ridge, the seal ridge having a concave curvature when viewed from a side elevation, the concave curvature corresponding to a deformation curve demonstrated by a flexible flap that has a first portion secured to a surface at as a cantilever and has a second, non-secured portion exposed to a uniform force, a force having a magnitude equal to the mass of the second portion of the flexible flap multiplied by at least one gravitational unit of acceleration, or a combination thereof; and

(b) attaching a first portion of the flexible flap to the valve seat such that (i) the flexible flap makes contact with the seal ridge when a fluid is not passing through the orifice, and (ii) the second portion of the attached flexible flap is free to be lifted from the seal ridge when a fluid is passing through the orifice.

Filtering face masks should be safe and comfortable to wear. To be safe, the face mask should not allow contaminants to enter the interior of the face mask through the exhalation valve, and to be comfortable, the face mask should displace as large a percentage of exhaled air as possible through the exhalation valve with minimal effort. The present invention provides a safe exhalation valve by having a flexible flap that makes a substantially uniform seal to the valve seat under any orientation of the exhalation valve. The present invention helps relieve discomfort to the wearer by (1) minimizing exhalation pressure inside a filtering face mask, (2) purging a greater percentage of

exhaled air through the exhalation valve (as opposed to having the exhaled air pass through the filter media), and under some circumstances (3) providing a negative pressure inside a filtering face mask during exhalation to create a net flow of cool, ambient air into the face mask.

In the first and fourth aspects of the present invention, a unidirectional fluid valve is provided that enables a flexible flap to exert a substantially uniform force on a seal ridge of the valve seat. The substantially uniform force is obtained by attaching a first portion of a flexible flap to a surface and suspending a second or free portion of the flexible flap as a cantilever beam. The second or free portion of the flexible flap is then deformed under computer simulation by applying a plurality of force vectors of the same magnitude to the flexible flap at directions normal to the curvature of the flexible flap. The second portion of the flexible flap takes on a particular curvature, referred to as the deformation curve. The deformation curve is traced, and that tracing is used to define the curvature of the seal ridge of the valve seat. A valve seat of this curvature prevents the flexible flap from buckling and from making slight or no contact with the seal ridge at certain locations and making too strong a contact at other locations. This uniform contacting relationship allows the valve to be safe by precluding the influx of contaminants.

In the first and fourth aspects of the present invention, a unidirectional fluid valve is also provided which minimizes exhalation pressure. This advantage is accomplished by achieving the minimum force necessary to keep the flexible flap in the closed position under any orientation. The minimum flap closure force is obtained by providing an exhalation valve with a valve seat that has a seal ridge with a concave curvature that corresponds to a deformation curve exhibited by the flexible flap when it is secured as a cantilever at one end and bends under its own weight. A seal ridge corresponding to this deformation curve allows the exhalation valve to remain closed when completely inverted but also permits it to be opened with minimum force to thereby lower the pressure drop across the face mask.

In the second aspect of the present invention, a filtering face mask is provided with an exhalation valve that can demonstrate a lower airflow resistance force, which enables the exhalation valve to open easier. This advantage has been accomplished in the present invention by securing the flexible flap to the valve seat outside the region encompassed by the valve orifice. An exhalation valve of this construction allows the flexible flap to be lifted more easily from the curved seal ridge because a greater moment arm is obtained when the flexible flap is mounted to the valve seat outside the region encompassed by the orifice. A further advantage of an exhalation valve of this construction is that it can allow the whole orifice to be open to airflow during an exhalation.

In addition to the above advantages, this invention allows a greater percentage of exhaled air to be purged through the exhalation valve, and, after an initial positive pressure to open the valve, allows the pressure inside the filtering face mask to decrease and in some cases become negative during exhalation. These two attributes have been achieved by (i) positioning the exhalation valve of this invention on a filtering face mask substantially directly opposite to where the wearer's mouth would be when the face mask is being worn, and (ii) defining a preferred cross-sectional area for the orifice of the exhalation valve. When an exhalation valve of this invention has an orifice with a cross-sectional area greater than about 2 square centimeters (cm^2) when viewed from a plane perpendicular to the direction of fluid flow and the exhalation valve is located on the filtering face mask substantially directly in front of the wearer's mouth, lower

and negative pressures can be developed inside of the filtering face mask during normal exhalation.

In this invention, at least 40 percent of the exhaled air can exit the face mask through the exhalation valve at a positive pressure drop of less than 24.5 pascals at low exhalation air velocities and volume airflows greater than 40 liters per minute (l/min). At higher exhalation air velocities (such as with the wearer's lips pursed), a negative pressure may be developed inside of the filtering face mask. In the third aspect of the present invention, a filtering face mask is provided that demonstrates a negative pressure. The negative pressure allows a volume of air greater than one hundred percent of the exhaled air to pass out through the exhalation valve, and further enables ambient air to pass inwardly through the filtering media when a person is exhaling. This creates a situation where upon the next inhalation the wearer breathes in cooler, fresher, ambient air of lower humidity than the wearer's breath and of higher oxygen content. The influx of ambient air is referred to as aspiration, and it provides the wearer of the face mask with improved comfort. The aspiration effect also reduces the fogging of eyewear because less exhaled air exits the face mask through the filter media. The discovery of the aspiration effect was very surprising.

The above novel features and advantages of the present invention are more fully shown and described in the drawings and the following detailed description, where like reference numerals are used to represent similar parts. It is to be understood, however, that the drawings and detailed description are for the purposes of illustration only and should not be read in a manner that would unduly limit the scope of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front view of a filtering face mask 10 in accordance with the present invention.

FIG. 2 is a partial cross-section of the face mask body 12 of FIG. 1.

FIG. 3 is a cross-sectional view of an exhalation valve 14 taken along lines 3—3 of FIG. 1.

FIG. 4 is a front view of a valve seat 18 in accordance with the present invention.

FIG. 5 is a side view of a flexible flap 24 suspended as a cantilever and being exposed to a uniform force.

FIG. 6 is a side view of a flexible flap 24 suspended as a cantilever as being exposed to gravitational acceleration, g.

FIG. 7 is a perspective view of a valve cover 50 in accordance with the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In describing preferred embodiments of this invention, specific terminology will be used for the sake of clarity. The invention, however, is not intended to be limited to the specific terms so selected, and it is to be understood that each term so selected includes all the technical equivalents that operate similarly.

FIG. 1 illustrates a filtering face mask 10 according to the present invention. Filtering face mask 10 has a cup-shaped mask body 12 to which an exhalation valve 14 is attached. Mask body 12 is provided with an opening (not shown) through which exhaled air can exit without having to pass through the filtration layer. The preferred location of the opening on the mask body 12 is directly in front of where the

wearer's mouth would be when the mask is being worn. Exhalation valve 14 is attached to mask body 12 at the location of that opening. With the exception of the location of the exhalation valve 14, essentially the entire exposed surface of mask body 12 is fluid permeable to inhaled air.

Mask body 12 can be of a curved, hemispherical shape or may take on other shapes as so desired. For example, the mask body can be a cup-shaped mask having a construction like the face mask disclosed in U.S. Pat. No. 4,827,924 to Japuntich. Mask body 12 may comprise an inner shaping layer 16 and an outer filtration layer 18 (FIG. 2). Shaping layer 16 provides structure to the mask 10 and support for filtration layer 18. Shaping layer 16 may be located on the inside and/or outside of filtration layer 18 and can be made, for example, from a nonwoven web of thermally-bondable fibers molded into a cup-shaped configuration. The shaping layer can be molded in accordance with known procedures. Although a shaping layer 16 is designed with the primary purpose of providing structure to the mask and support for a filtration layer, shaping layer 16 also may provide for filtration, typically for filtration of larger particles. To hold the face mask snugly upon the wearer's face, mask body can have straps 20, tie strings, a mask harness, etc. attached thereto. A pliable dead soft band 22 of metal such as aluminum can be provided on mask body 12 to allow it to be shaped to hold the face mask in a desired fitting relationship on the nose of the wearer.

When a wearer of a filtering face mask 10 exhales, exhaled air passes through the mask body 12 and exhalation valve 14. Comfort is best obtained when a high percentage of the exhaled air passes through exhalation valve 14, as opposed to the filter media of mask body 12. Exhaled air is expelled through valve 14 by having the exhaled air lift flexible flap 24 from valve seat 26. Flexible flap 24 is attached to valve seat 26 at a first portion 28 of flap 24, and the remaining circumferential edge of flexible flap 24 is free to be lifted from valve seat 26 during exhalation. As the term is used herein, "flexible" means the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., FIG. 5). A flap that is not self-supporting will tend to drape towards the ground at about 90 degrees from the horizontal.

As shown in FIGS. 3 and 4, valve seat 26 has a seal ridge 30 to which the flexible flap 24 makes contact when a fluid is not passing through the valve 14. An orifice 32 is located radially inward to seal ridge 30 and is circumscribed thereby. Orifice 32 can have cross-members 34 that stabilize seal ridge 30 and ultimately valve 14. The cross-members 34 also can prevent flexible flap 24 from inverting into orifice 32 under reverse air flow, for example, during inhalation. When viewed from a side elevation, the surface of the cross-members 34 is slightly recessed beneath (but may be aligned with) seal ridge 30 to ensure that the cross members do not lift the flexible flap 24 off seal ridge 30 (see FIG. 3).

Seal ridge 30 and orifice 32 can take on any shape when viewed from a plane perpendicular to the direction of fluid flow (FIG. 4). For example, seal ridge 30 and orifice 32 may be square, rectangular, circular, elliptical, etc. The shape of seal ridge 30 does not have to correspond to the shape of orifice 32. For example, the orifice 32 may be circular and the seal ridge may be rectangular. It is only necessary that the seal ridge 30 circumscribe the orifice 32 to prevent the undesired influx of contaminants through orifice 32. The seal ridge 30 and orifice 32, however, preferably have a circular cross-section when viewed against the direction of fluid flow. The opening in the mask body 12 preferably has a cross-sectional area at least the size of orifice 32. The

flexible flap 24, of course, covers an area larger than orifice 32 and is at least the size of the area circumscribed by seal ridge 30. Orifice 32 preferably has a cross-sectional area of 2 to 6 cm², and more preferably 3 to 4 cm². An orifice of this size provides the face mask with an aspiration effect to assist in purging warm, humid exhaled air. An upper limit on orifice size can be important when aspiration occurs because a large orifice provides a possibility that ambient air may enter the face mask through the orifice of the exhalation valve, rather than through the filter media, thereby creating unsafe breathing conditions.

FIG. 3 shows flexible flap 24 in a closed position resting on seal ridge 30 and in an open position by the dotted lines 24a. Seal ridge 30 has a concave curvature when viewed in the direction of FIG. 3. This concave curvature, as indicated above, corresponds to the deformation curve displayed by the flexible flap when it is secured as a cantilever beam. The concave curvature shown in FIG. 3 is inflection free, and preferably extends along a generally straight line in the side-elevational direction of FIG. 3. A fluid passes through valve 14 in the direction indicated by arrow 36. The apex of the concave curvature is located upstream to fluid flow through the annular orifice 32 relative to the outer extremities of the concave curvature. Fluid 36 passing through annular orifice 32 exerts a force on flexible flap 24 causing free end 38 of flap 24 to be lifted from seal ridge 30 of valve seat 26 making valve 14 open. Valve 14 is preferably oriented on face mask 10 such that the free end 38 of flexible flap 24 is located below secured end 28 when the mask 10 is positioned upright as shown in FIG. 1. This enables exhaled air to be deflected downwards so as to prevent moisture from condensing on the wearer's eyewear.

As shown in FIGS. 3 and 4, valve seat 26 has a flap-retaining surface 40 located outside the region encompassed by orifice 32 beyond an outer extremity of seal ridge 30. Flap-retaining surface 40 preferably traverses valve 14 over a distance at least as great as the width of orifice 32. Flap-retaining surface 40 may extend in a straight line in the direction to which surface 40 traverses the valve seat 26. Flap-retaining surface 40 can have pins 41 for holding flexible flap 24 in place. When pins 41 are employed as part of a means for securing flexible flap 24 to valve seat 26, flexible flap 24 would be provided with corresponding openings so that flexible flap 24 can be positioned over pins 41 and preferably can be held in an abutting relationship to flap-retaining surface 40. Flexible flap 24 also can be attached to the flap-retaining surface by sonic welding, an adhesive, mechanical clamping, or other suitable means.

Flap-retaining surface 40 preferably is positioned on valve seat 40 to allow flexible flap 24 to be pressed in an abutting relationship to seal ridge 30 when a fluid is not passing through orifice 32. Flap-retaining surface 40 can be positioned on valve seat 26 as a tangent to the curvature of the seal ridge 30 when viewed from a side elevation (FIG. 3). The flap-retaining surface 40 is spaced from orifice 32 and seal ridge 30 to provide a moment arm that assists in the deflection of the flap during an exhalation. The greater the spacing between the flap-retaining surface 40 and the orifice 32, the greater the moment arm and the lower the torque of the flexible flap 24 and thus the easier it is for flexible flap 24 to open when a force from exhaled air is applied to the same. The distance between surface 40 and orifice 32, however, should not be so great as to cause the flexible flap to dangle freely. Rather, the flexible flap 24 is pressed towards seal ridge 30 so that there is a substantially uniform seal when the valve is in the closed position. The distance between the flap-retaining surface and nearest portion of

orifice 32, preferably, is about 1 to 3.5 mm, more preferably 1.5 to 2.5 mm.

The space between orifice 32 and the flap-retaining surface 40 also provides the flexible flap 24 with a transitional region that allows the flexible flap 24 to more easily assume the curve of the seal ridge 30. Flexible flap 24 is preferably sufficiently supple to account for tolerance variations. Flap-retaining surface 40 can be a planar surface or it can be a continuous extension of curved seal ridge 30; that is, it can be a curved extension of the deformation curve displayed by the flexible flap. As such, however, it is preferred that flexible flap 24 have a transitional region between the point of securing and the point of contact with seal ridge 30.

Valve seat 26 preferably is made from a relatively light-weight plastic that is molded into an integral one-piece body. The valve seat can be made by injection molding techniques. The surface of the seal ridge 30 that makes contact with the flexible flap 24 (the contact surface) is preferably fashioned to be substantially uniformly smooth to ensure that a good seal occurs. The contact surface preferably has a width great enough to form a seal with the flexible flap 24 but is not so wide as to allow adhesive forces caused by condensed moisture to significantly make the flexible flap 24 more difficult to open. The width of the contact surface, preferably, is at least 0.2 mm, and preferably is in the range of about 0.25 mm to 0.5 mm.

Flexible flap 24 preferably is made from a material that is capable of displaying a bias toward seal ridge 30 when the flexible flap 24 is secured to the valve seat 26 at surface 40. The flexible flap preferably assumes a flat configuration where no forces are applied and is elastomeric and is resistant to permanent set and creep. The flexible flap can be made from an elastomeric material such as a crosslinked natural rubber (for example, crosslinked polyisoprene) or a synthetic elastomer such as neoprene, butyl rubber, nitrile rubber, or silicone rubber. Examples of rubbers that may be used as flexible flaps include: compound number 40R149 available from West American Rubber Company, Orange, Calif.; compounds 402A and 330A available from Arizt-Optibelt-KG, Höxter, Germany; and RTV-630 available from General Electric Company, Waterford, N.Y. A preferred flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal ridge under any static orientation for twenty-four hours at 70° C.; see European Standard for the European Committee for Standardization (CEN) Europäische Norm (EN) 140 part 5.3 and 149 parts 5.2.2 for a test that measures stress relaxation under these conditions. The flexible flap preferably provides a leak-free seal according to the standards set forth in 30 C.F.R. §11.183-2 (Jul. 1, 1991). A crosslinked polyisoprene is preferred because it exhibits a lesser degree of stress relaxation. The flexible flap typically will have a Shore A hardness of about 30 to 50.

Flexible flap 24 may be cut from a flat sheet of material having a generally uniform thickness. In general, the sheet has a thickness of about 0.2 to 0.8 mm; more typically 0.3 to 0.6 mm, and preferably 0.35 to 0.45 mm. The flexible flap is preferably cut in the shape of a rectangle, and has a free end 38 that is cut to correspond to the shape of the seal ridge 30 where the free end 38 makes contact therewith. For example, as shown in FIG. 1, free end 38 has a curved edge 42 corresponding to the circular seal ridge 30. By having the free end 38 cut in such a manner, the free end 38 weighs less and therefore can be lifted more easily from the seal ridge 30 during exhalation and closes more easily when the face mask is inverted. The flexible flap 24 preferably is greater

than about 1 cm wide, more preferably in the range of about 1.2 to 3 cm wide, and is about 1 to 4 cm long. The secured end of the flexible flap typically will be about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the valve seat 26. A preferred flexible flap of this invention is about 2.4 cm wide and about 2.6 cm long and has a rounded free end 38 with a radius of about 1.2 cm.

As best shown in FIGS. 1 and 4, a flange 43 extends laterally from the valve seat 26 to provide a surface onto which the exhalation valve 14 can be secured to the mask body 12. Flange 43 preferably extends around the whole perimeter of valve seat 26. When the mask body 12 is a fibrous filtration face mask, the exhalation valve 14 can be secured to the mask body 12 at flange 43 by sonic welds, adhesion bonding, mechanical clamping, or the like. It is preferred that the exhalation valve 14 be sonically welded to the mask body 12 of the filtering face mask 10.

A preferred unidirectional fluid valve of this invention is advantageous in that it has a single flexible flap 24 with one free end 38, rather than having two flaps each with a free end. By having a single flexible flap 24 with one free end 38, the flexible flap 24 can have a longer moment arm, which allows the flexible flap 24 to be more easily lifted from the seal ridge 30 by the dynamic pressure of a wearer's exhaled air. A further advantage of using a single flexible flap with one free end is that the exhaled air can be deflected downward to prevent fogging of a wearer's eyewear or face shield (e.g. a welder's helmet).

FIG. 5 illustrates a flexible flap 24 deformed by applying a uniform force to the flexible flap. Flexible flap 24 is secured at a first portion 28 to a hold-down surface 46 and has for a second or free portion suspended therefrom as a cantilever beam. Surface 46 desirably is planar, and the flexible flap 24 is preferably secured to that planar surface along the whole width of portion 28. The uniform force includes a plurality of force vectors 47 of the same magnitude, each applied at a direction normal to the curvature of the flexible flap. The resulting deformation curve can be used to define the curvature of a valve seat's seal ridge 30 to provide a flexible flap that exerts a substantially uniform force upon the seal ridge.

Determining the curvature of a seal ridge 30 that provides a substantially uniform seal force is not easily done empirically. It can, however, be determined numerically using finite element analysis. The approach taken is to model a flexible flap secured at one end with a uniform force applied to the free end of the flexible flap. The applied force vectors are kept normal to the curvature of flexible flap 24 because the seal force executed by flexible flap 24 to the seal ridge 30 will act normal thereto. The deformed shape of flexible flap 24 when subjected to this uniform, normal force is then used to fashion the concave curvature of seal ridge 30.

Using finite element analysis, the flexible flap can be modelled in a two-dimensional finite element model as a bending beam fixed at one end, where the free end of the flexible flap is divided into numerous connected subregions or elements within which approximate functions are used to represent beam deformation. The total beam deformation is derived from linear combinations of the individual element behavior. The material properties of the flexible flap are used in the model. If the stress-strain behavior of the flexible flap material is non-linear, as in elastomeric materials, the Mooney-Rivlin model can be used (see, R. S. Rivlin and D. W. Saunders (1951), Phil. Trans. R. Soc. A243, 251-298 "Large Elastic Deformation of Isotropic Materials: VII

Experiments on the Deformation of Rubber"). To use the Mooney-Rivlin model, a set of numerical constants that represent the stress/strain behavior of the flexible flap need to be determined from experimental test data. These constants are placed into the Mooney-Rivlin model which is then used in the two-dimensional finite element model. The analysis is a large deflection, non-linear analysis. The numerical solution typically is an iterative one, because the force vectors are kept normal to the surface. A solution is calculated based upon the previous force vector. The direction of the force vector is then updated and a new solution calculated. A converged solution is obtained when the deflected shape is not changing from one iteration to the next by more than a preset minimum tolerance. Most finite element analysis computer programs will allow a uniform force to be input as an elemental pressure which is ultimately translated to nodal forces or input directly as nodal forces. The total magnitude of the nodal forces may be equal to the mass of the free portion of the flexible flap multiplied by the acceleration of gravity acting on the mass of the flexible flap or any factor of gravity as so desired. Preferred gravitational factors are discussed below. The final X, Y position of the deflected nodes representing the flexible flap can be curve fit to a polynomial equation to define the shape of the concave seal ridge.

FIG. 6 illustrates a flexible flap 24 being deformed by gravity, g. The flexible flap 24 is secured as a cantilever beam at end 28 to surface 46 of a solid body 48. Being secured in this fashion, flexible flap 24 displays a deformation curve caused by the acceleration of gravity, g. As indicated above, the side-elevational curvature of a valve seat's seal ridge can be fashioned to correspond to the deformation curve of the flexible flap 24 when exposed to a force in the direction of gravity which is equal to the mass of the free portion of the flexible flap 24 multiplied by at least one unit of gravitational acceleration, g.

A gravitational unit of acceleration, g, has been determined to be equal to a 9.807 meters per second per second (m/s^2). Although a seal ridge having a curvature that corresponds to a deformation curve exhibited by a flexible flap exposed to one g can be sufficient to hold the flexible flap in a closed position, it is preferred that the seal ridge have a curvature that corresponds to a deformation curve exhibited by a flexible flap that is exposed to a force caused by more than one g of acceleration, preferably 1.1 to 2 g. More preferably, the seal ridge has a curvature that corresponds to the flexible flap's deformation curve at from 1.2 to 1.5 g of acceleration. A most preferred seal ridge has a side-elevational curvature that corresponds to a deformation curve exhibited by a flexible flap exposed to a force caused by 1.3 g of acceleration. The additional gravitational acceleration is used to provide a safety factor to ensure a good seal to the valve seat at any face mask orientation, and to accommodate flap thickness variations and additional flap weight caused by condensed moisture.

In actual practice, it is difficult to apply a preload exceeding 1 g (e.g., 1.1, 1.2, 1.3 g etc.) to a flexible flap. The deformation curve corresponding to such mounts of gravitational acceleration, however, can be determined through finite element analysis.

To mathematically describe a flexible flap bending due to gravity, the two-dimensional finite element model is defined to be constrained at one end in all degrees of freedom. A set of algebraic equations are solved, yielding the beam deformation at the element nodes of interest, which, when combined, form the entire deformation curve. A curve-fit to these points gives an equation for the curve, and this equation can be used to generate the seal ridge curvature of the valve seat.

The versatility of finite element analysis is that the magnitude of the gravitational constant's acceleration and direction can be varied to create the desired pre-load on a flexible flap. For instance, if a pre-load of 10 percent of the weight of the flexible flap is needed, the deformation curve generated at 1.1 g would be used as the side-elevational curvature of the seal ridge. The direction may be changed by rotating the gravitational acceleration vector with respect to a horizontal hold-down surface or by rotating the hold-down surface with respect to the gravitational vector. Although a suitable deformation curve can be determined by having hold-down surface 46 parallel to the horizontal, it was found in the research leading to this design that the greatest deformation of the flexible flap 24 does not occur when the flexible flap 24 is supported at the horizontal, but when the flexible flap 24 is held elevated above the horizontal as shown in FIG. 5 and the hold-down surface 46 is at an angle θ in the range of 25 to 65 degrees. It was discovered that by rotating the hold-down surface at an angle to the horizontal, a deformation curve can be generated that closely approximates a deformation curve having been subjected to uniform forces normal to the curved flap. For a fixed flexible flap length, the best rotational angle θ is dependent upon the magnitude of the gravitational constant and the thickness of the flexible flap. In general, however, a preferred deformation curve can be displayed by having hold-down surface 46 at an angle θ of about 45 degrees.

The mathematical expression that defines the deformation curve of a flexible flap exposed to either a uniform force and/or a force of a factor of at least one unit of gravitational acceleration is a polynomial mathematical expression, typically a polynomial mathematical expression of at least the third order. The particular polynomial mathematical expression that defines the deformation curve can vary with respect to parameters such as flexible flap thickness, length, composition, and the applied force(s) and direction of those force(s).

Exhalation valve 14 can be provided with a valve cover to protect the flexible flap 24, and to help prevent the passage of contaminants through the exhalation valve. In FIG. 6, a valve cover 50 is shown which can be secured to exhalation valve 14 by a fiction fit to wall 44. Valve cover 50 also can be secured to the exhalation valve 14 by ultrasonic welding, an adhesive, or

other suitable means. Valve cover 50 has an opening 52 for the passage of a fluid. Opening 52 preferably is at least the size of orifice 32, and preferably is larger than orifice 32. The opening 52 is placed, preferably, on the valve cover 50 directly in the path of fluid flow 36 so that eddy currents are minimized. In this regard, opening 52 is approximately parallel to the path traced by the free end 38 of flexible flap 24 during its opening and closing. As with the flexible flap 24, the valve cover opening 52 preferably directs fluid flow downwards so as to prevent the fogging of a wearer's eyewear. All of the exhaled air can be directed downwards by providing the valve cover with fluid-impermeable side walls 54. Opening 52 can have cross-members 56 to provide structural support and aesthetics to valve cover 50. A set of ribs 58 can be provided on valve cover 50 for further structural support and aesthetics. Valve cover 50 can have its interior fashioned such that there are female members (not shown) that mate with pins 41 of valve seat 14. Valve cover 50 also can have a surface (not shown) that holds flexible flap 24 against flap-retaining surface 40. Valve cover 50 preferably has fluid impermeable ceiling 60 that increases in height in the direction of the flexible flap from the fixed end to the free end. The interior of the ceiling 60 can be provided

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with a ribbed or coarse pattern or a release surface to prevent the free end of the flexible flap from adhering to the ceiling 60 when moisture is present on the ceiling or the flexible flap. The valve cover design 50 is fully shown in U.S. Des. patent application Ser. No. 29/000,382. Another valve cover that also may be suitable for use on a face mask of this invention is shown in Des. patent application Ser. No. 29/000,384. The disclosures of these applications are incorporated here by reference.

Although the unidirectional fluid valve of this invention has been described for use as an exhalation valve, it also can be possible to use the valve in other applications, for example as an inhalation valve for a respirator or as a purge valve for garments or positive pressure helmets.

Advantages and other features of this invention are further illustrated in the following examples. It is to be expressly understood, however, that while the examples serve this purpose, the materials selected and amounts used, as well as other conditions and details, are not to be construed in a manner that would unduly limit the scope of this invention.

EXAMPLE 1

(Finite Element Analysis: Flexible Flap Exposed to 1.3 g)

In this Example, finite element analysis was used to define the curvature of a valve seat's seal ridge. The curvature corresponded to the deformation curve exhibited by the free portion of a flexible flap after being exposed to 1.3 g of acceleration. The flexible flap was composed of a natural rubber compound containing 80 weight percent polyisoprene, 13 weight percent zinc oxide, 5 weight percent of a long-chain fatty acid ester as a plasticizer, stearic acid, and an antioxidant. The flexible flap had a material density of 1.08 grams per cubic centimeter (g/cm^3), an ultimate elongation of 670 percent, an ultimate tensile strength of 19.1 meganewtons per square meter, and a Shore A harness of 35. The flexible flap had a free-swinging length of 2.4 cm, a width of 2.4 cm, a thickness of 0.43 mm, and a rounded free end with a radius of 1.2 cm. The total length of the flexible flap was 2.8 cm. The flexible flap was subjected to a tensile test, a pure shear test, and a biaxial tension test to give three data sets of actual behavior. This data was converted to engineering stress and engineering strain. The Mooney-Rivlin constants were then generated using the finite element ABAQUS computer program (available from Hibbit, Karlsson and Sorensen, Inc., Pawtucket, R.I.). After checking computer simulations of the stress/strain tests against the empirical data, the two Mooney-Rivlin constants were determined to be 24.09 and 3.398. These constants gave the closest numerical results to the actual data from the tests on the flexible flap material.

Input parameters describing the grid points, boundary conditions, and load were chosen, and those parameters and the Mooney-Rivlin constants were then inserted into the ABAQUS finite element computer program. The shape function of the individual elements was selected to be quadratic with mid-side nodes. The gravitational constant was chosen to be 1.3 g. The angle of rotation θ from the horizontal for a maximum deformation curvature was determined to be 34 degrees by rotating the gravitational vector. A regression of the data gave a curve for the valve seat defined by the following equation:

$$y=+0.052559x-2.445429x^2+5.785336x^3-16.625961x^4+13.787755x^5$$

where x and y are the abscissa and the ordinate, respectively. The correlation coefficient squared was equal to 0.99, indicating an excellent correlation of this equation to the finite element analysis data.

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A valve seat was machined from aluminum and was provided with a seal ridge that had a side-elevational curvature which corresponded to the above deformation curve. A circular orifice of 3.3 cm^2 was provided in the valve seat. The flexible flap was clamped to a flat flap-retaining surface. The flap-retaining surface was spaced 1.3 mm from the nearest portion of the orifice tangential to the curved seal ridge. The flap-retaining surface was 6 mm long, and traversed the valve seat for a distance of 25 mm. The curved seal ridge had a width of 0.51 mm. The flexible flap remained in an abutting relationship to the seal ridge no matter how the valve was oriented. The seal between the flexible flap and the valve seat was found to be leak-free.

The minimum force required to open this valve was then determined. This was accomplished by attaching the valve to a fluid-permeable mask body, taping the valve shut, and monitoring the pressure drop as a function of airflow volume. After a plot of pressure drop versus airflow was obtained for a filtering face mask with the valve taped shut, the same was done for the filtering face mask with the valve open. The two sets of data were compared. The point where the two sets of data diverged represented the initial opening of the valve. After many repetitions, the average opening pressure drop was determined to be 1.03 mmH_2O . This pressure was converted to the force to levitate the flexible flap by dividing the pressure needed to open the valve by the area of flexible flap within the orifice. The area of the flexible flap within the orifice was 3.49 cm^2 . This gave an opening force of 0.00352 Newtons. The weight of the free-swinging part of the flexible flap was 0.00251 Newtons, and the ratio of the opening force to the weight gave an operational preload of 1.40 g. This quantity is close to the chosen gravitational constant 1.3 g, and the extra force may be taken to be the force needed to bend the flexible flap during opening.

EXAMPLE 2

(Finite Element Analysis: Flexible Flap Exposed to a Uniform Force)

In this Example, finite element analysis was employed to define a valve seat where the flexible flap would exert a uniform force on the seal ridge of the valve seat. The flexible flap that was used in this Example was the same as the flexible flap of Example 1. The ABAQUS computer program of Example 1 was used in the finite element analysis. The analysis was a large deflection, non-linear analysis. The force factors that were used in the analysis were kept normal to the surface of the flexible flap. An iterative calculation was employed: a curve was calculated based on the previous force vectors, and that curve was updated and a new curve was then obtained. The converged numerical equation for the curve was obtained when the

deformation did not change significantly from one iteration to the next. The final curvature was translated into the following fifth order, polynomial equation:

$$y=0.01744x-1.26190x^2+0.04768x^3-1.83595x^4+2.33781x^5$$

where x and y are the abscissa and ordinate, respectively.

EXAMPLE 3

(Finite Element Analysis: Flexible Flap Exposed to 1.3 g)

In this Example, as in Example 1, finite element analysis was used to define the curvature of a valve seat's seal ridge which corresponds to the curvature of a free portion of a

flexible flap which was exposed to 1.3 g of acceleration. This Example differs from Example 1 in that the flexible flap was made from compound 330A, available from Arizt-Optibelt KG. The flexible flap had a material density of 1.07 grams per cubic centimeter (g/cm^3), an ultimate elongation greater than 600%, an ultimate tensile strength of 17 meganewtons per square meter, and a Shore A hardness of 47.5. The geometry of the flap was the same as for the flap in Example 1. When the rubber was subjected to the same testing as in Example 1, the Mooney-Rivlin constants were determined to be 53.47 and -0.9354. The first constant shows this material to be stiffer than that of Example 1, also shown in greater Shore A hardness.

When a 0.43 mm thick flap made from this material was installed on the valve seat of Example 1, the rubber sealed uniformly across the entire valve seat curve. However, because of the greater stiffness of this material, the opening pressure drop was slightly higher than the material in Example 1. When a thinner flap of 0.38 mm was installed to lower this pressure drop, this lower thickness did not lie uniformly across the valve seat, lifting up slightly in the middle of the curve. However, the flap could be made to lie uniformly and leak-free across the valve seat by either moving the flap-retaining surface closer or by slightly altering the curve of Example 1 to make it shallower.

The ABAQUS program was used in Example 1 to obtain deformation curves for this material. The gravitational constant was chosen to be 1.3 g to yield a deformation curve having a pre-load of 30 percent of the weight of the flexible flap. In this case, the angles of rotation θ from the horizontal for a maximum deformation curvature were determined to be 40 degrees and 32 degrees for the flap thicknesses of 0.38 mm and 0.43 mm, respectively. Regression of the data gave curves for the valve seat having the following fourth order polynomial equations, for 0.38 mm thick flap:

$$y = -0.03878x - 0.91868x^2 - 1.13096x^3 + 1.21551x^4$$

and for a 0.43 mm thick flap:

$$y = 0.00287x - 1.03890x^2 + 0.19674x^3 + 0.20014x^4$$

where x and y are the abscissa and ordinate, respectively.

These curves are shallower than the curve obtained for the rubber of Example 1, showing that the pre-load of the rubber of this Example when applied to the valve seat curve of Example 1 will be greater than 30 percent.

EXAMPLE 4-6

(Comparison of Valve of '362 Patent with Valve of this Invention)

In Examples 4-6, the exhalation valve of this invention was compared to the exhalation valve of the '362 patent. In Example 4, the exhalation valve of Example 1 was tested for the valve's airflow resistance force by placing the exhalation valve at the opening of a pipe having a cross-sectional area of 3.2 cm^2 and measuring the pressure drop with a manometer. An airflow of 85 l/min was passed through the pipe. The measured pressure drop was multiplied by the flexible flap's surface area over the orifice to obtain the airflow resistance force. The data gathered is set forth in Table 1.

Examples 5 and 6 correspond to examples 2 and 4 of the '362 patent, respectively. In examples 2 and 4 of the '362 patent, the length and width of the flaps were changed, and each valve was tested for its pressure drop at 85 liters per minute (l/min) through the same nozzle of Example 4.

TABLE I

Example	Orifice Area (cm^2)	Pressure Drop (Pascals)	Airflow Resistance Force (Newtons)
4	5.3	26.46	0.0140
5*	5.3	60.76	0.0322
6*	13.5	17.64	0.0238

*Comparative examples corresponding to examples 2 and 4 of the '362 patent, respectively.

In Table 1, the data demonstrates that the exhalation valve of this invention (Example 4) has less airflow resistance force than the exhalation valve of the '362 patent (Examples 5-6).

EXAMPLE 7

(Aspiration Effect)

In this Example, a normal exhalation test was employed to demonstrate how an exhalation valve of this invention can create a negative pressure inside a face mask during exhalation.

A "normal exhalation test" is a test that simulates normal exhalation of a person. The test involves mounting a filtering face mask to a 0.5 centimeter (cm) thick flat metal plate that has a circular opening or nozzle of 1.61 square centimeters (cm^2) ($\frac{1}{16}$ inch diameter) located therein. The filtering face mask is mounted to the flat, metal plate at the mask base such that airflow passing through the nozzle is directed into the interior of the mask body directly towards the exhalation valve (that is, the airflow is directed along the shortest straight line distance from a point on a plane bisecting the mask base to the exhalation valve). The plate is attached horizontally to a vertically-oriented conduit. Air flow sent through the conduit passes through the nozzle and enters the interior of the face mask. The velocity of the air passing through the nozzle can be determined by dividing the rate of airflow (volume/time) by the cross-sectional area of the circular opening. The pressure drop can be determined by placing a probe of a manometer within the interior of the filtering face mask.

The exhalation valve of Example 1 was mounted to a 3M 8810 filtering face mask such that the exhalation valve was positioned on the mask body directly opposite to where a wearer's mouth would be when the mask is worn. The airflow through the nozzle was increased to approximately 80 l/min to provide an airflow velocity of 0.9 meters per second (m/s). At this velocity, zero pressure drop was achieved inside the face mask. An ordinary person will exhale at moderate to heavy work rates at an approximate air velocity of about 0.5 to 1.3 m/s depending on the opening area of the mouth. Negative and relatively low pressures can be provided in a face mask of this invention over a large portion of this range of air velocity.

EXAMPLES 8-13

(Filtering Face Mask of this Invention—Measure of Pressure Drop and Percent Total Flow Through the Exhalation Valve as a Function Total Airflow Through Face Mask)

The efficiency of the exhalation valve to purge breath as a percentage of total exhalation flow at a certain pressure drop is a major factor affecting wearer comfort. In Examples 7-12, the exhalation valve of Example 1 was tested on a 3M 8810 filtering face mask, which at 80 l/min flow has a pressure drop of about 63.7 pascals. The exhalation valve

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was positioned on the mask body directly opposite to where a wearer's mouth would be when the mask is worn. The pressure drop through the valve was measured as described in Example 7 at different vertical volume flow rates, using airflow nozzles of different cross-sectional areas.

The percent total flow was determined by the following method. First, the linear equation describing the filter media volume flow (Q_f) relationship with the pressure drop (ΔP) was found with the valve held closed by correlating experimental data from positive and negative pressure drop data (note: when the pressure drop is positive, Q_f is also positive). The pressure drop with the valve allowed to open was then measured at a specified exhalation volume flow (Q_T). The flow through the valve alone (Q_v) is calculated as $Q_v = Q_T - Q_f$, with Q_f calculated at that pressure drop. The percent of the total exhalation flow through the valve is calculated by $100(Q_v/Q_T)Q_T$. If the pressure drop on exhalation is negative, the inward flow of air through the filter media into face mask will also be negative, giving the condition that the flow out through the valve orifice Q_v is greater than the exhalation flow Q_T . The data for pressure drop and percent total flow are set forth in Table 2.

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the illustrated embodiments set forth above but is to be controlled by the limitations set forth in the claims and any equivalents thereof.

What is claimed is:

1. A method of making a unidirectional fluid valve, which method comprises:

(a) providing a valve seat that has an orifice circumscribed by a seal ridge, the seal ridge having a concave curvature when viewed from a side elevation, the concave curvature corresponding to a deformation curve demonstrated by a flexible flap that has a first portion secured to a surface at as a cantilever and has a second, non-secured portion exposed to (i) a uniform force that acts along the length of the deformation curve normal thereto, (ii) a force acting in the direction of gravity and having a magnitude equal to the mass of the second portion of the flexible flap multiplied by at least one gravitational unit of acceleration, or a combination of (i) and (ii); and

(b) attaching a first portion of the flexible flap to the valve seat such that (i) the flexible flap makes contact with the seal ridge when a fluid is not passing through the

TABLE 2

Examples	Volume Flow (liters/minute)	Pressure Drop (Pa) Nozzle Area: 1.81 cm ²	Pressure Drop (Pa) Nozzle Area: 2.26 cm ²	Pressure Drop (Pa) Nozzle Area: 0.96 cm ²	% Total Flow Nozzle Area: 18.1 cm ²	% Total Flow Nozzle Area: 2.26 cm ²	% Total Flow Nozzle Area: 0.95 cm ²
8	12	9.02	8.92	8.92	1	2	2
9	24	15.09	14.21	11.17	19	24	39
10	48	18.62	14.99	4.31	30	60	87
11	60	20.48	15.09	-1.76	56	68	102
12	72	22.34	14.80	-7.55	61	73	112
13	80	24.01	14.41	-12.94	62	77	119

35

In Table 2, the data shows that for low momentum airflows an increase in airflow causes an increase in pressure drop (18.1 cm² nozzle). Low momentum airflows are rare in typical face mask usage. Nonetheless, the percent total flow is greater than 50 percent at above approximately 30 l/min (Examples 10-13). A typical person will exhale at about 25 to 90 l/min depending on the person's work rate. On average, a person exhales at about 32 l/min. Thus, the face mask of this invention provides good comfort to a wearer at low momentum airflows.

At higher momentum airflows (obtained using a 2.26 cm² nozzle), an increase in airflow causes a lower pressure drop than the 18.1 cm² nozzle. As the airflow is increased, the effect of aspiration becomes apparent as the pressure drop reaches a maximum and then begins to decrease with increasing airflow. The percent total flows through the exhalation valve increase with higher airflows to greater than 70 percent, thereby providing better comfort to the wearer.

At the highest momentum airflows (using a 0.95 cm² nozzle), the pressure drop increases slightly and then decreases to negative quantifies as airflow increases. This is the aspiration effect and is shown in Table 2 as percent total flow quantities that are greater than 100 percent. For instance, in Example 13 the percent total flow at 80 l/min is 119 percent: where 19 percent of the total volume flow is drawn through the filter media into the interior of the face mask and is expelled out through the exhalation valve.

Various modifications and alterations of this invention may become apparent to those skilled in the art without departing from the invention's scope. It therefore should be understood that the invention is not to be unduly limited to

orifice, and (ii) the second portion of the attached flexible flap is free to be lifted from the seal ridge when a fluid is passing through the orifice.

2. The method of claim 1, wherein the concave curvature corresponds to a deformation curve exhibited by the flexible flap when exposed to the uniform force that is not less than the mass of the second portion of the flexible flap multiplied by at least one gravitational unit of acceleration.

3. The method of claim 1, wherein the concave curvature corresponds to a deformation curve exhibited by the flexible flap when exposed to the uniform force in the range of the mass of the second portion of the flexible flap multiplied by 1.1 to 1.5 g of acceleration.

4. The method of claim 1, wherein the flexible flap has a stress relaxation sufficient to keep the second portion of the flexible flap in leak-free contact to the seal ridge under any static orientation for twenty-four hours at 70° C. when a fluid is not passing through the orifice.

5. The method of claim 1, wherein the flexible flap comprises crosslinked polyisoprene, is 0.35 to 0.45 millimeters thick, and has a Shore A hardness 30 to 50.

6. The method of claim 1, wherein the first portion of the flexible flap is attached to the valve seat beyond the area encompassed by the orifice.

7. The method of claim 1, wherein the concave curvature of the seal ridge is defined by a polynomial mathematical equation of at least the third order.

8. The method of claim 1, wherein the orifice has a cross-sectional area in the range of 2 to 6 cm² when viewed from a plane perpendicular to the direction of fluid flow.

9. The method of claim 38, wherein the orifice is 3 to 4 cm² in size.

10. The method of claim 1, wherein the first portion of the flexible flap is attached to a flap-retaining surface located on the exterior of the orifice beyond an outer extremity of the curved seal ridge, the point attachment being 1 to 3.5 mm from the curved seal ridge.

11. The method of claim 10, wherein the flap-retaining surface traverses the valve seat over a distance at least as great as the width of the orifice, and the flat retaining surface extends in a straight line in the direction to which the flap-retaining surface traverses the valve seat.

12. The method of claim 1, wherein the concave curvature corresponds to the deformation curve exhibited by the second portion of the flexible flap when exposed to a force acting in the direction of gravity and having a magnitude equal to a mass of the second portion of the flexible flap multiplied by 1.1 to 2 g of acceleration.

13. The method of claim 12, wherein the concave curvature correspond to the deformation curve exhibited by the second portion of the flexible flap when exposed to a force

having a magnitude equal to a mass of the second portion of the flexible flap multiplied by 1.2 to 1.5 g of acceleration.

14. The method of claim 13, wherein the concave curvature corresponds to the deformation curve exhibited by the flexible flap when exposed to a force having a magnitude equal to a mass of the second portion of the flexible flap multiplied by 1.3 g of acceleration.

15. The method of claim 12, wherein the deformation curve corresponds to the deformation curve exhibited by the second portion of the flexible flap when secured at the first portion at an angle θ to the horizontal in the range of 25 to 65 degrees.

16. The unidirectional fluid valve of claim 15, wherein the angle θ is about 45°.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO.: 5,509,436

DATED: April 23, 1996

INVENTOR(S): Daniel A. Japuntich et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 9, line 6, "dement" should be --element--.

Col. 14, line 48, "801/min" should be --80 //min--.

Col. 15, line 57, "quantifies" should be --quantities--.

Col. 16, line 66, "38" should be --8--.

Col. 18, line 16, delete "unidirectional fluid valve" and insert therefor --method--.

Signed and Sealed this

Seventeenth Day of September, 1996

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO.: 5,509,436

DATED: April 23, 1996

INVENTOR(S): Daniel A. Japuntich et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 2, line 33, "0.8" should read --8--.

Col. 14, line 48, "0.9" should read --8.3--.

Col. 14, line 52, "0.5 to 1.3" should read --5 to 13--.

Col. 15, in Table 2, Column 3 heading, "1.81 cm" should read --18.1 cm²--.

Signed and Sealed this
Second Day of June, 1998

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks



UNITED STATES PATENT AND TRADEMARK OFFICE

Due Date: 9-27-08
12-27-08

Already Docketed: CAR

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100.56842 010 ✓

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,943	06/25/2001	William A. Mittelstadt	56842US002 ✓	9282
32692	7590	08/06/2008	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY			PATEL, NIHIR B	
PO BOX 33427			ART UNIT	PAPER NUMBER
ST. PAUL, MN 55133-3427			3772	
			NOTIFICATION DATE	DELIVERY MODE
			08/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/888,943	Applicant(s) MITTELSTADT ET AL.
	Examiner NIHIR PATEL	Art Unit 3772

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED July 9th, 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
 - a) The period for reply expires 3 months from the mailing date of the final rejection.
 - b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 - (a) They raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) They raise the issue of new matter (see NOTE below);
 - (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. Applicant's reply has overcome the following rejection(s): _____.
6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 27-47 and 49-71.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. Other: _____.

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772

/Nihir Patel/
Examiner, Art Unit 3772

The applicant argues that Lubeck does not teach a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask. The examiner disagrees with the applicant's argument. Lubeck does teach a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask. Figure 1 of the Lubeck reference shows a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask (the spots where reference characters 1 and 24 are pointing at define a curvature from the first end 24 to a second end 1). The applicant further argues that Lubeck does not describe a unidirectional valve where at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening. First the valve of Lubeck is unidirectional as stated on page 2 ("These valve closure bodies are not under tension whatsoever for closed valves and open in any direction indicating unidirectional. Figure 5 shows that at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening.



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100-56842-010 ✓

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,943	06/25/2001	William A. Mittelstadt	56842US002	9282
32692	7590	06/27/2008	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY			PATEL, NIHIL B	
PO BOX 33427				
ST. PAUL, MN 55133-3427				
Due: 8/27/08			ART UNIT	PAPER NUMBER
9/27/08			3772	
12/27/08				
Docketed: JD			NOTIFICATION DATE DELIVERY MODE	
			06/27/2008 ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)
	09/888,943	MITTELSTADT ET AL.
	Examiner NIHIR PATEL	Art Unit 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03.28.2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-47 and 49-71 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 27-47 and 49-71 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 28th, 2008 have been fully considered but they are not persuasive. The applicant argues that Lübeck does not teach a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask. The examiner disagrees with the applicant's argument. Lübeck does teach a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask. Figure 1 of the Lübeck reference shows a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask (the spots where reference characters 1 and 24 are pointing at define a curvature from the first end 24 to a second end 1).

The examiner acknowledges the cancellation of claim 16. In reference to claim 27 the examiner has addressed this claim see page 2 section 8 of the office action dated November 29th, 2007.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 27-32, 34-42, 44-55, 57-65 and 67-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Lübeck (1213249).

4. As to claim 28, Lübeck discloses an apparatus that comprises a facemask having at least one opening for receiving a unidirectional valve (see page 2 4th paragraph); and a

unidirectional valve comprising valve body (see **figure 1**) comprising a valve opening; and a valve flap 1 (see **figure 1**) having a first portion attached to the frame and an adjacent second portion that seals the valve opening (see **figure 1**), wherein the valve flap has curvature from the first end spaced from the second end when the valve flap is not attached (see **last paragraph on page 1**) to the valve body, and further wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening (see **figure 1**).

5. **As to claims 29 and 52**, Lübeck discloses an apparatus wherein the valve opening is generally planar, and wherein the valve flap curvature biases the valve flap toward the valve opening when the valve flap is attached to the valve body to seal the valve opening (see **figure 1**).
6. **As to claims 30 and 53**, Lübeck discloses an apparatus wherein the valve flap curvature biases the valve flap toward the valve opening to seal the valve opening, and wherein the bias of the valve flap toward the valve opening is sufficient to seal between the valve opening in any orientation of the unidirectional valve (see **figure 1**).
7. **As to claim 27**, Lübeck discloses an apparatus wherein the valve flap is removably attached to the valve body (see **page 3 paragraph 2**).
8. **As to claims 31 and 54**, Lübeck discloses an apparatus wherein the curvature in the valve flap comprises a constant curvature from the first end to the second end (see **last paragraph on page 1**).
9. **As to claims 32 and 55**, Lübeck discloses an apparatus wherein the curvature in the valve flap varies from the first end to the second end (see **last paragraph on page 1**).

10. **As to claims 34 and 57,** Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (see page 2 3rd paragraph).
11. **As to claims 35 and 58,** Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (see page 2 3rd paragraph).
12. **As to claims 36 and 59,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, and at least one support element 2 extending from the top surface of the valve flap (see figure 1), wherein the at least one support element provides the curvature shape of the valve flap (see figures 1 and 2) that is at least partially flattened when the valve flap seals the valve opening (see figure 1).
13. **As to claims 37 and 60,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, wherein the valve flap further comprises plurality of support elements 4, 5 and 6 extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support elements (see figure 2), and wherein the plurality of support elements provide the curvature shape of the valve flap (see figures 1 and 2) that is at least partially flattened when the valve flap seals the valve opening (see figure 1).
14. **As to claims 38 and 61,** Lübeck discloses an apparatus that comprises a facemask (see page 2 4th paragraph) comprising an opening formed therethrough; and a unidirectional valve located over the opening in the facemask, the unidirectional valve comprising a valve flap 1 attached to the facemask over the opening (see figure 1), the valve flap comprising a curvature from a first end to a second end when the valve flap is not attached to the facemask, wherein the curvature of the valve flap is at least partially flattened when the valve flap seals the opening in the facemask (see figure 1).

15. **As to claims 39 and 62,** Lübeck discloses an apparatus wherein the at least partially flattened curvature of the valve flap creates a bias that is substantial enough to keep the valve flap sealed over the opening in all orientations (**see figure 1**).
16. **As to claims 40 and 63,** Lübeck discloses an apparatus wherein the curvature in the valve flap comprises a constant curvature (**see last paragraph on page 1**).
17. **As to claims 41 and 64,** Lübeck discloses an apparatus wherein the curvature in the valve flap varies from the first end to the second end (**see last paragraph on page 1**).
18. **As to claims 42 and 65,** Lübeck discloses an apparatus wherein the opening is generally planar and the curvature of the valve flap attached to the facemask over the opening is flattened when the valve flap seals the opening in the facemask (**see figure 1**).
19. **As to claims 44 and 67,** Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (**see page 2 3rd paragraph**).
20. **As to claims 45 and 68,** Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (**see page 2 3rd paragraph**).
21. **As to claims 46 and 69,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, and at least one support element 2 extending from the top surface of the valve flap (**see figure 1**), wherein the at least one support element provides the curvature shape of the valve flap (**see figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).
22. **As to claims 47 and 71,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, wherein the valve flap further comprises plurality of support elements 4, 5 and 6 extending from the top surface, wherein each of the plurality of

support elements is spaced from each adjacent support elements (**see figure 2**), and wherein the plurality of support elements provide the curvature shape of the valve flap (**see figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).

23. **As to claim 49**, Lübeck discloses an apparatus wherein the valve flap comprises a cantilevered valve flap and wherein the first portion of the valve flap is attached to the frame of the valve opening (**see figures 1 and 3**).

24. **As to claim 50**, Lübeck discloses an apparatus wherein the valve flap comprises a cantilevered valve flap, and wherein the first end of the cantilevered valve flap is attached to the facemask (**see figures 1 and 3**).

25. **As to claim 51**, Lübeck discloses an apparatus that comprises a face mask; and a unidirectional valve (**see page 2 4th paragraph**) attached to the face mask over an opening formed through the face mask (**see figure 1**), wherein the unidirectional valve comprises (**see figure 1**): a valve body comprising a valve opening; and a cantilevered valve flap comprising a first end attached to the valve body and a second end located opposite from the first end (**see figure 1**), wherein the first end of the valve flap is attached to the valve body outside of the valve opening, and wherein the valve flap comprises a curvature from the first end to the second end when the valve flap is not attached to the valve body (**see last paragraph on page 1**), and further wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening.

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3772

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. Claims **33, 43, 56 and 66** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lübeck (1213249) in view of Japuntich et al. (US 5,509,436).

29. **As to claims 33, 43, 56 and 66**, Lübeck substantially discloses the claimed invention , see rejection of claims 15, 28 and 38 above, but does not disclose a facemask that is formed of a filtering material. Japuntich discloses an apparatus that does provide a facemask that is formed of a filtering material (**see column 5 lines 10-15**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lübeck's invention by providing a facemask that is formed of a filtering material as taught by Japuntich in order to filter large particles.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. **Claims 28, 38 and 48-50** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **13-16 and 26** of U.S. Patent No. 6,883,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 28 and 38 of the current application and claims 13 and 26 of the patent '518 lies in the fact that the patent claims 13 and 26 includes many more elements and is thus much more specific. Thus the invention of claims 13 and 26 is in effect a "species" of the "generic" invention of claims 28 and 38 of the current application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (fed. Cir. 1993). Since claims 28 and 38 of the current application is anticipated by claims 13 and 26 of patent '518, it is not patentably distinct from claims 13 and 26 of patent '518. **Claim 48 of the current application**, the limitations can be found in claim 26 of patent '518. **Claim 49 of the current application**, the limitations can be found in claim 26 of patent '518. **Claim 50 of the current application**, the limitations can be found in claim 26 of patent '518.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,943 ✓	06/25/2001 ✓	William A. Mittelstadt	56842US002 100-54842010	9282 ✓
32692	7590	11/29/2007	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			PATEL, NIHIL B	
		ART UNIT	PAPER NUMBER	
		3772		
NOTIFICATION DATE	DELIVERY MODE			
11/29/2007	ELECTRONIC			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)
	09/888,943 ✓	MITTELSTADT ET AL.
	Examiner	Art Unit
	Nihir Patel	3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10.31.2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-47 ad 49-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 27-47 and 49-71 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10.31.2007.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31st, 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed on October 31st, 2007 have been fully considered but they are not persuasive. The applicant argues that Lübeck does not disclose a valve flap having a curvature from the first end to the second end when the valve flap is not attached to the valve body as stated in claim 28 or when the valve flap is not attached to the face mask as stated in claim 38. The examiner disagrees. Lübeck does disclose a valve flap having a curvature from the first end to the second end when the valve flap is not attached to the valve body as stated in claim 28 or when the valve flap is not attached to the face mask as stated in claim 38 (**see figures 3 and 6**).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 28-32, 34-42, 44-55, 57-65 and 67-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Lübeck (1213249).

5. As to claim 28, Lübeck discloses an apparatus that comprises a facemask having at least one opening for receiving a unidirectional valve (see page 2 4th paragraph); and a unidirectional valve comprising valve body (see figure 1) comprising a valve opening; and a valve flap 1 (see figure 1) having a first portion attached to the frame and an adjacent second portion that seals the valve opening (see figure 1), wherein the valve flap has curvature from the first end spaced from the second end when the valve flap is not attached (see last paragraph on page 1) to the valve body, and further wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening (see figure 1).

6. As to claims 29 and 52, Lübeck discloses an apparatus wherein the valve opening is generally planar, and wherein the valve flap curvature biases the valve flap toward the valve opening when the valve flap is attached to the valve body to seal the valve opening (see figure 1).

7. As to claims 30 and 53, Lübeck discloses an apparatus wherein the valve flap curvature biases the valve flap toward the valve opening to seal the valve opening, and wherein the bias of the valve flap toward the valve opening is sufficient to seal between the valve opening in any orientation of the unidirectional valve (see figure 1).

8. As to claim 27, Lübeck discloses an apparatus wherein the valve flap is removably attached to the valve body (see page 3 paragraph 2).

9. **As to claims 31 and 54,** Lübeck discloses an apparatus wherein the curvature in the valve flap comprises a constant curvature from the first end to the second end (see last paragraph on page 1).

10. **As to claims 32 and 55,** Lübeck discloses an apparatus wherein the curvature in the valve flap varies from the first end to the second end (see last paragraph on page 1).

11. **As to claims 34 and 57,** Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (see page 2 3rd paragraph).

12. **As to claims 35 and 58,** Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (see page 2 3rd paragraph).

13. **As to claims 36 and 59,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, and at least one support element 2 extending from the top surface of the valve flap (see figure 1), wherein the at least one support element provides the curvature shape of the valve flap (see figures 1 and 2) that is at least partially flattened when the valve flap seals the valve opening (see figure 1).

14. **As to claims 37 and 60,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, wherein the valve flap further comprises plurality of support elements 4, 5 and 6 extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support elements (see figure 2), and wherein the plurality of support elements provide the curvature shape of the valve flap (see figures 1 and 2) that is at least partially flattened when the valve flap seals the valve opening (see figure 1).

15. **As to claims 38 and 61,** Lübeck discloses an apparatus that comprises a facemask (see page 2 4th paragraph) comprising an opening formed therethrough; and a unidirectional valve

located over the opening in the facemask, the unidirectional valve comprising a valve flap 1 attached to the facemask over the opening (see figure 1), the valve flap comprising a curvature from a first end to a second end when the valve flap is not attached to the facemask, wherein the curvature of the valve flap is at least partially flattened when the valve flap seals the opening in the facemask (see figure 1).

16. **As to claims 39 and 62,** Lübeck discloses an apparatus wherein the at least partially flattened curvature of the valve flap creates a bias that is substantial enough to keep the valve flap sealed over the opening in all orientations (see figure 1).

17. **As to claims 40 and 63,** Lübeck discloses an apparatus wherein the curvature in the valve flap comprises a constant curvature (see last paragraph on page 1).

18. **As to claims 41 and 64,** Lübeck discloses an apparatus wherein the curvature in the valve flap varies from the first end to the second end (see last paragraph on page 1).

19. **As to claims 42 and 65,** Lübeck discloses an apparatus wherein the opening is generally planar and the curvature of the valve flap attached to the facemask over the opening is flattened when the valve flap seals the opening in the facemask (see figure 1).

20. **As to claims 44 and 67,** Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (see page 2 3rd paragraph).

21. **As to claims 45 and 68,** Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (see page 2 3rd paragraph).

22. **As to claims 46 and 69,** Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, and at least one support element 2 extending from the top surface of the valve flap (see figure 1), wherein the at least one support element provides

the curvature shape of the valve flap (see **figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (see **figure 1**).

23. **As to claims 47 and 71**, Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, wherein the valve flap further comprises plurality of support elements **4, 5 and 6** extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support elements (see **figure 2**), and wherein the plurality of support elements provide the curvature shape of the valve flap (see **figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (see **figure 1**).

24. **As to claim 49**, Lübeck discloses an apparatus wherein the valve flap comprises a cantilevered valve flap and wherein the first portion of the valve flap is attached to the frame of the valve opening (see **figures 1 and 3**).

25. **As to claim 50**, Lübeck discloses an apparatus wherein the valve flap comprises a cantilevered valve flap, and wherein the first end of the cantilevered valve flap is attached to the facemask (see **figures 1 and 3**).

26. **As to claim 51**, Lübeck discloses an apparatus that comprises a face mask; and a unidirectional valve (see page 2 4th paragraph) attached to the face mask over an opening formed through the face mask (see **figure 1**), wherein the unidirectional valve comprises (see **figure 1**): a valve body comprising a valve opening; and a cantilevered valve flap comprising a first end attached to the valve body and a second end located opposite from the first end (see **figure 1**), wherein the first end of the valve flap is attached to the valve body outside of the valve opening, and wherein the valve flap comprises a curvature from the first end to the second end when the valve flap is not attached to the valve body (see last paragraph on page 1), and

further wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claims 16, 33, 43, 56 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lübeck (1213249) in view of Japuntich et al. (US 5,509,436).

30. As to claims 16, 33, 43, 56 and 66, Lübeck substantially discloses the claimed invention, see rejection of claims 15, 28 and 38 above, but does not disclose a facemask that is formed of a filtering material. Japuntich discloses an apparatus that does provide a facemask that is formed of a filtering material (see column 5 lines 10-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lübeck's invention

by providing a facemask that is formed of a filtering material as taught by Japuntich in order to filter large particles.

Double Patenting

31. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. Claims **28, 38 and 48-50** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **13-16 and 26** of U.S. Patent No. 6,883,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 28 and 38 of the current application and claims 13 and 26 of the patent ‘518 lies in the fact that the patent claims 13 and 26 includes many more elements and is thus much more specific. Thus the invention of claims 13 and 26 is in effect a “species” of the “generic” invention of claims 28 and 38 of the current application. It has been held that the

generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (fed. Cir. 1993). Since claims 28 and 38 of the current application is anticipated by claims 13 and 26 of patent ‘518, it is not patentably distinct from claims 13 and 26 of patent ‘518. **Claim 48 of the current application, the limitations can be found in claim 26 of patent ‘518. Claim 49 of the current application, the limitations can be found in claim 26 of patent ‘518. Claim 50 of the current application, the limitations can be found in claim 26 of patent ‘518.**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
09/888,943
Art Unit: 3772

Page 10

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Art Unit 3772

Nihir Patel

Nihir Patel

Patricia Bianco
PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
11/26/07

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OCT 31 2007

INFORMATION DISCLOSURE STATEMENT <small>OCT 31 2007 PATENT & TRADEMARK OFFICE</small>		OMB No. 0551-0011					
		Atty. Docket No.: 56842US002	Serial No.: 09/188,943				
		Applicant(s): William A. Mittelstadt, David M. Magidson and Thomas L. Insley					
Filing Date: June 25, 2001		Group: 3761					
U.S. PATENT DOCUMENTS							
Examiner Initials	Document Number	Date	Name	Class	SubClass	Filing Date If Appropriate	
/NP/	2,999,498	09/12/61	Matheson				
	4,414,973	11/15/83	Matheson et al.				
	4,630,604	12/23/86	Montesi				
	4,850,346	07/25/89	Michel et al.				
	4,934,362	06/19/90	Braun				
	4,958,633	09/25/90	Angell				
	4,974,586	12/04/90	Wandel et al.				
	4,981,134	01/01/91	Courtney				
V	5,325,892	07/05/94	Japuntich et al.				
	6,047,698	04/11/00	Magidson et al.				
/NP/	D413,166	08/24/99	Snow et al.				
FOREIGN PATENT DOCUMENTS							
Document Number	Date of Publication	Country	Class	SubClass	Translation		
/NP/ 0 252 890	01/13/88	EPO			Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
/NP/ 0 252 891	01/13/88	EPO			Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)							
EXAMINER		Date Considered					
/Nihir Patel/		11/25/2007					
* Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							
Based on Form PTO-FB-1820 (Also Form PTO-1449) q:\Jmp\co\forms and samples\do\1449.doc 4/1/99							
Patent and Trademark Office, U.S. Department of Commerce							

OCT 3 1 2007

Substitute for form 1449A/PTO (modified)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

O/P/E

(Use as many sheets as necessary)

FEB 2 0 2003

Page 1 of 1

Application Number	09/888943
Filing Date	June 25, 2001
First Named Inventor	Mittelstadt, William A.
Art Unit	3743
Examiner Name	Nihir B. Patel
Attorney Case Number	66842US002

U.S. Patent Documents

Exam. Init.*	Cite No.	Document Number	Publication Date or Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Column, Lines, Where Relevant Passages or Relevant Figures Appear
		Doc. Number-(Kind Code if Known)			
/NP/	A1	US- RE37,974E	02-04-2003	Bowers	
	A2	US-			
	A3	US-			
	A4	US-			
	A5	US-			
	A6	US-			
	A7	US-			
	A8	US-			
	A9	US-			
	A10	US-			
	A11	US-			

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Foreign Patent Documents

Exam. Init.*	Cite No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Column, Lines, Where Relevant Passages or Relevant Figures Appear	Translation (Check if yes)
		Ctry. Code	Number-Kind Code (if known)				
	B1						
	B2						
	B3						
	B4						
	B5						
	B6						
	B7						

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	
	C2	
	C3	

*Examiner: /Nihir Patel/

Date Considered: 11/25/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

Information Disclosure Statement — PTO-1449 (Modified)

04/12/2004 15:43 FAX 6123051228

MUETING RAASCH GEBHARDT

0014

OMB No. 0651-0011
Page 1 of 1

INFORMATION DISCLOSURE STATEMENT	Atty. Docket No.: 56842US002	Serial No.: 09/888,943
	Applicant(s): MITTLESTADT et al.	Confirmation No.: 9282
	Application Filing Date: 25 June 2001	Group: 3743
	Information Disclosure Statement mailed:	May 12, 2004

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Applicable
/NP/	2002/0195108 A1	12/26/02	Mittlestadt et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation Yes No
	NONE					

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Document Description
	NONE

EXAMINER	Date Considered
/Nihir Patel/	11/25/2007

* Examiner's Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citations if not in conformance and not considered. Include copy of this form with next communication to applicant.

PAGE 14/25 *RCVD AT 4/12/2004 4:40:48 PM [Eastern Daylight Time]* SVR:USPTO-EFXRF-1/10* DNIS:8729306* CSID:6123051228* DURATION (mm:ss):07:42

PAGE 22/22 *RCVD AT 10/31/2007 4:18:19 PM [Eastern Daylight Time]* SVR:USPTO-EFXRF-1/8* DNIS:2738300* CSID:6123051228* DURATION (mm:ss):06:16

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: MITTELSTADT, WILLIAM A.

Application No.: 09/888943 Group Art Unit: 3743

Filed: June 25, 2001 Examiner: Nihir B. Patel

Title: RESPIRATOR VALVE

DUE DATE(S)
Kerr
pre
NO DUE DATE

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on:	
September 5, 2002	Signed by: Susan M. Dacko
Date	

Dear Sir:

Pursuant to 37 CFR §§ 1.56, 1.97, and 1.98, enclosed is a completed Form PTO-1449, citing references submitted for consideration by the Examiner. A copy of each cited reference is also enclosed. It is respectfully requested that the Examiner initial and return the enclosed Form PTO-1449 to indicate that each reference has been considered.

Applicants bring to the Examiner's attention the following applications, copies of which are enclosed:

1. U.S. Serial No. 09/442,082 to Bowers filed November 15, 1999 entitled *Uni-Directional Fluid Valve*.
2. U.S. Serial No. 09/986,346 to Bowers filed November 8, 2001 entitled *Uni-Directional Fluid Valve*.
3. U.S. Serial No. 08/240,877 to Japuntich et al. filed May 23, 1995 entitled *Filtering Face Mask That Has A New Exhalation Valve*.
4. U.S. Serial No. 09/677,637 to Japuntich et al. filed October 3, 2000 entitled *Fibrous Filtration Face Mask Having A New Unidirectional Fluid Valve*, which is a continuation of U.S. Serial No. 08/240,877.
5. U.S. Serial No. 09/678,579 to Japuntich et al. filed October 3, 2000 entitled *Fibrous Filtration Face Mask Having A New Unidirectional Fluid Valve*, which is a continuation of U.S. Serial No. 08/240,877.

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SEP 10 2002

6. U.S. Serial No. 09/677,915 to Japuntich et al. filed October 3, 2000 entitled *Fibrous Filtration Face Mask Having A New Unidirectional Fluid Valve*, which is a continuation of U.S. Serial No. 08/240,877.

7. U.S. Serial No. 09/678,580 to Japuntich et al. filed October 3, 2000 entitled *Fibrous Filtration Face Mask Having A New Unidirectional Fluid Valve*, which is a continuation of U.S. Serial No. 08/240,877.

8. U.S. Serial No. 09/837,714 to Japuntich et al. filed April 18, 2001 entitled *Filtering Face Mask That Has A New Exhalation Valve*, which is a continuation of U.S. Serial No. 08/240,877.

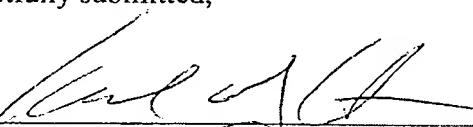
9. U.S. Serial No. 09/837,800 to Japuntich et al. filed April 18, 2001 entitled *Filtering Face Mask That Has A New Exhalation Valve*, which is a continuation of U.S. Serial No. 08/240,877.

For the Japuntich et al cases, applicants are only furnishing the Examiner with a copy of the '877 application, as the divisional applications are the same.

This Information Disclosure Statement is being mailed after receipt of a first Office Action on the merits, but prior to the mailing of a Notice of Allowance under 37 CFR § 1.311. Please charge the fee for consideration of an Information Disclosure Statement set forth in 37 CFR § 1.17(p) to Deposit Account No. 13-3723, and if necessary, please charge any additional fees, or credit any overpayment to Deposit Account No. 13-3723. One copy of this sheet marked duplicate is also enclosed.

Respectfully submitted,

September 5, 2002
Date

By: 
Karl G. Hanson, Reg. No.: 32,900
Telephone No.: 651-736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
P.O. Box 33427
St. Paul, MN 55133-3427
Facsimile No.: 651-736-3833

Substitute for form 1449A/PTO (Rev. 7-2001)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Page 1 of 1

Application Number 09/888943

Filing Date June 25, 2001

First Named Inventor Mittelstadt, William A.

Art Unit 3743

Examiner Name Nihir B. Patel

Attorney Case Number 56842US002

U.S. Patent Documents

Exam. Init.*	Cite No.	Document Number	Publication Date or Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Doc. Number-(Kind Code if Known)			
A1	US- 5,687,767		11-18-1997	Bowers	
A2	US-				
A3	US-				
A4	US-				
A5	US-				
A6	US-				
A7	US-				
A8	US-				
A9	US-				
A10	US-				
A11	US-				

Foreign Patent Documents

Exam. Init.*	Cite No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation (Check if yes)
		Ctry. Code	Number-KindCode (if known)				
B1							
B2							
B3							
B4							
B5							
B6							
B7							

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	
	C2	
	C3	

*Examiner:

Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

First Named Inventor: MITTE STAUT, WILLIAM A.

Case No.: 56842US002

Application No.: 09/888943

Title: RESPIRATOR VALVE

Enclosures:

Information Disclosure Statement, Form PTO-1449, and
cited references.

Amount charged to Deposit Account: \$180.00

Attorney (initials): KGH

Date: September 5, 2002



PATENT
Docket No. 56842US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): MITTLESTADT et al.) Group Art Unit: 3772
Serial No.: 09/888,943)
Confirmation No.: 9282) Examiner: Nihir B. Patel
Filed: 25 June 2001)
For: RESPIRATOR VALVE)

RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As discussed below, Applicants request reconsideration and withdrawal of the rejections set forth in the Office Action dated 29 November 2007.

Status of the Claims

The pending claims are claims 27-47 and 49-71. Rejected claims 27-47 and 49-71 are the subject of this request.

Reconsideration is requested for the following reasons:

Applicants submit that clear errors, as discussed below, exist in the Examiner's rejection, and/or the Examiner's omission of one or more essential elements needed for a *prima facie* anticipation rejection.

Claims 28, 38, and 48-50 were rejected on the ground of non-statutory obvious-type double patenting as being unpatentable over claims 13-16 and 26 of U.S. Patent No. 6883, 518. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

Claims 28-32, 34-42, 44-55, 57-65, and 67-71 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Lübeck (DE 1213249).

Claims 16, 33, 43, 56, and 66 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lübeck in view of Japuntich et al. (U.S. Pat. No. 5,509,436).

(Please note that Applicants are unclear as to why claim 16 is being rejected because claim 16 was canceled in the Amendment and Response dated 31 Oct. 2007. Further, please note that Applicants are unclear as to the status of claim 27 as it does not appear to have been addressed in the Detailed Action of the Office Action.)

The Examiner has clearly erred in rejecting independent claims 28, 38, 51, and 61 (from which the rest of the claims depend) under 35 U.S.C. § 102(b) as being anticipated by Lübeck because Lübeck does not teach or suggest all the claim elements recited in the rejected claims.

For example, Lübeck does not teach a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask as recited in independent claims 28, 38, 51, and 61. Lübeck, instead, teaches valve flaps that only have a flat shape. See *Lübeck*, Figures 1, 5-7.

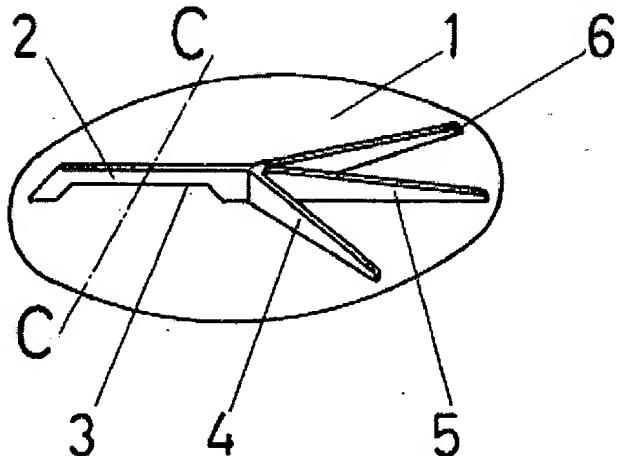
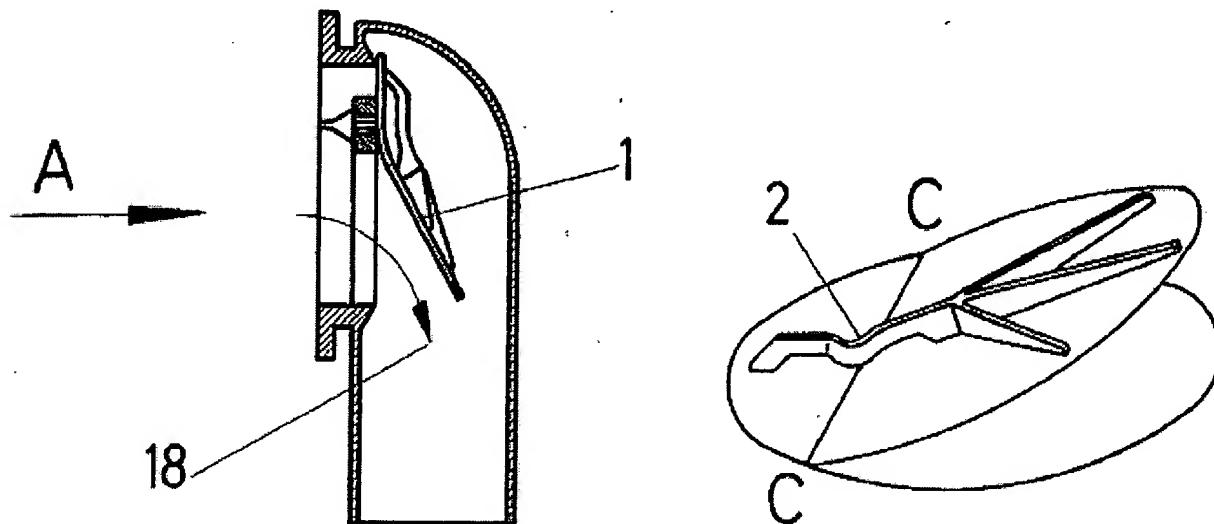


Figure 5 of Lübeck.

In response to these arguments, it is asserted in the Office Action that Figures 3 and 6 of Lübeck, in particular, show the claimed curvature in the valve flap. *See Office Action, 29 Nov. 2007, page 2 ("The examiner disagrees. Lübeck does disclose a valve flap having a curvature from the first end to the second end when the valve flap is not attached to the valve body as stated in claim 28 or when the valve flap is not attached to the face mask as stated in claim 38 (see figures 3 and 6).")*.



Figures 3 & 6, respectively, of Lübeck.

Although the valve flaps in Figures 3 and 6 of Lübeck are curved in Figures 3 & 6, the valve flaps are being forced open by airflow in both figures. As a result, any characterization of Figures 3 and 6 of Lübeck as depicting a valve flap that has curvature when it is not attached to another structure is factually wrong.

As support for Applicants' position that Figures 3 and 6 of Lübeck show valve flaps being forced open by airflow, please note the following sentence found in the third paragraph after the figure descriptions on page 3 of the Lübeck Translation: "As shown in Fig. 3 and 6, the bridge 3 of rib 2 bends sideways for an opened valve." In other words, the valve flaps that are depicted in Figures 3 and 6 of Lübeck have been deflected into the curved shape by air pressure to open the valve in which they are located when, e.g., a user exhales.

Applicants' position that the valve flaps of Figures 3 and 6 of Lübeck are being deflected is further reinforced by Figure 5 of Lübeck (shown above), which shows a flat valve flap. The flat valve flap shown in Figure 5 is same valve flap as shown in Figure 6 except that in Figure 6, the valve flap is open, and therefore deflected, as evidenced by the following sentence found on the third line on page 3 of the Lübeck Translation: "Fig. 6 the closure body of Fig. 5 in open state."

As a result, it is factually incorrect to assert that Lübeck teaches a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask as would be required for *prima facie* anticipation rejection of independent claims 28, 38, 51, and 61.

Pre-Appeal Brief Request for Review
Serial No.: 09/888,943
Confirmation No.: 9282
Filed: 25 June 2001
For: RESPIRATOR VALVE

Page 5 of 5

Summary

For at least the above reasons, Applicants assert that the reasons provided demonstrate clear errors in the Examiner's rejection, and/or the Examiner's omission of one or more essential elements needed for a *prima facie* anticipation rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the anticipation rejection of claims 27-47 and 49-71 in the above-identified application.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228

28 MAR. 2008

Date

By: 
Kevin W. Raasch
Reg. No. 35,651
Direct Dial (612) 305-1218

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28th day of March, 2008, at 11:34 am (Central Time).

By: Dani Monroe
Name: Dani Monroe

Appeal Due: 09/27/08
Docketed -- SRD

**RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP: 3772**

32692

Customer Number

Patent
Case No.: 56842US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: MITTELSTADT, WILLIAM A.

Application No.: 09/888943 Confirmation No.: 9282

Filed: June 25, 2001

Title: RESPIRATOR VALVE

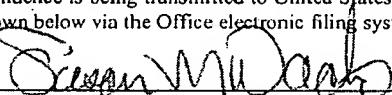
AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF TRANSMISSION [37 CFR § 1.8(a)]

I hereby certify that this correspondence is being transmitted to United States Patent and Trademark Office on the date shown below via the Office electronic filing system.

July 9, 2008
Date


Signed by: Susan M. Dacko

Dear Sir:

This is in response to the outstanding Office Action, dated June 27, 2008, in the above-identified application.

Fees

- Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.
- Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.
- Please credit any overpayment to the same deposit account.

REMARKS

Claims 27-32, 34-42, 44-55, 57-65, and 60 7-71 have been rejected under 35 USC § 102(b) as being anticipated by German Patent 1,213,249 to Lübeck. In making this rejection, the Examiner contends that Lübeck describes a valve flap that has "a curvature from the first end to a second end when not attached to the valve body or the facemask." More particularly, the Examiner states that "Figure 1 of the Lübeck reference shows a valve flap having a curvature from a first end to a second end when not attached to the valve body or the face mask (the spots where reference characters 1 and 24 are pointing at define a curvature from the first end 24 to a second end 1)."

Lübeck's Figure 1, however, does not show a valve flap that "has a curvature from a first end to a second end when the valve flap is not attached to the valve body". Lübeck only shows that its valve element has a slight curvature at ends 24 and 1:

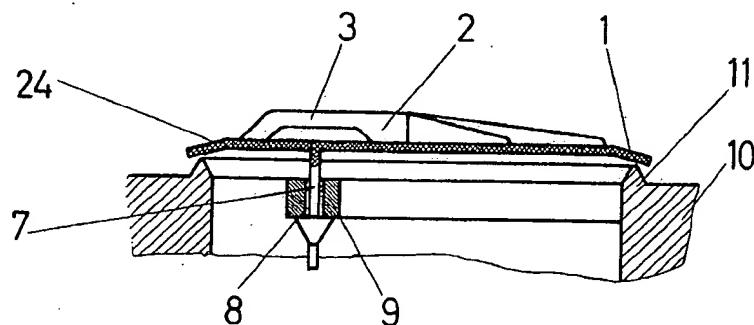


Figure 1 of Lübeck.

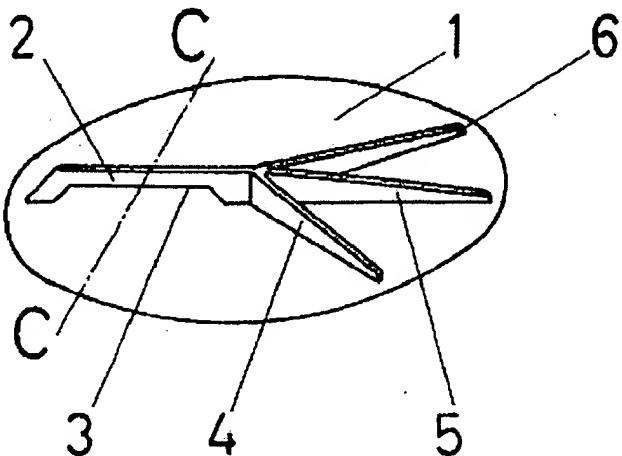


Figure 5 of Lübeck.

In addition, Lübeck does not describe a unidirectional valve where "at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening." On page 11 of their specification, applicants explain that the "at least partially flattening out" of the flap "provides the necessary sealing force to keep the valve diaphragm 56 in its closed position when not subjected to other forces." Thus, applicants' invention pertains to the use of a valve flap that is curved from a first end to a second end where a portion of the curvature becomes flattened out when the valve flap seals the opening. This particular flattening out of the flap is beneficial in that it enables a bias to be created, which provides the necessary sealing force to keep the valve diaphragm closed.

Not only does Lübeck fail to teach or suggest the structure of applicants invention so as to anticipate it under 35 USC § 102(a), but it also provides no teaching that would have rendered applicants' invention obvious to a person of ordinary skill, within the meaning of 35 USC § 103(a). As indicated above, Lübeck fails to teach two important features of applicants' invention. And it also fails to address the benefits that those features provide.

The secondary reference to US patent 5,509,436 to Japuntich et al. (Japuntich) adds little or nothing to what is lacking in Lübeck. Japuntich also fails to suggest providing a valve flap that is curved when not attached to the valve body and that becomes at least partially flattened out when the valve flap seals the opening.

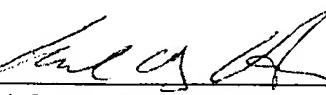
Claims 28, 38, and 48-50 have been rejected on the ground of non-statutory obvious-type double patenting as being unpatentable over claims 13-16 and 26 of U.S. Patent No. 6,883, 518. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

Please further examine this patent application in light of the remarks provided above.

Respectfully submitted,

July 9, 2008

Date

By: 
Karl G. Hanson, Reg. No.: 32,900

Telephone No.: 651-736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

Source: USPQ, 2d Series (1986 - Present) > U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences > Ex parte Levy, 17 USPQ2d 1461 (Bd. Pat. App. & Int. 1990)

Ex parte Levy, 17 USPQ2d 1461 (Bd. Pat. App. & Int. 1990)

17 USPQ2d 1461

Ex parte Levy

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences

No. 90-1864

Decided October 16, 1990

Headnotes

PATENTS

[1] Patentability/Validity - Anticipation - Identity of elements (► 115.0704)

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

[2] Patentability/Validity - In general (► 115.01)

Patentability/Validity - Anticipation - Prior art (► 115.0703)

Initial burden of establishing *prima facie* basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

[3] Patentability/Validity - Anticipation - Prior art (► 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

[4] Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (► 115.0903.03)

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition

Page 1461

Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812,

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filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof.
From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary

Page 1462

examiner), applicant appeals. Reversed.

Attorneys

Louis H. Rombach, Wilmington, Del., for appellant.

Judge

Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*
25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*

The references relied upon by the examiner

are: Wyeth et al. (Wyeth) 3,733,309 May 15, 1973

Schjeldahl et al.

(Schjeldahl '989) 4,413,989 Nov. 8, 1983¹

Schjeldahl et al.

(Schjeldahl '000) 4,456,000 June 26, 1984²

¹ Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner. .

² See footnote 1.

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. § 102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada*, —F.2d —, 15 USPQ2d 1655 (Fed.Cir. 1990); *In re Bond*, —F.2d —, 15 USPQ2d 1566 (Fed.Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed.Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed.Cir. 1988); *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1 USPQ2d 1337 (Fed.Cir. 1986); *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 730 F.2d 1452, 221 USPQ 481 (Fed.Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. § 102, the examiner is obliged to point out where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states

he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states

rguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied).

The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

(a) an expander ³formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material

(column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);

Page 1463

³ Schjeldahl characterizes the catheter balloon as an expander.

(b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented* polypropylene, *by an injection blow molding operation* and, as such, is

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substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);

(c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);

(d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);

(e) the expander 30 is formed *from a biaxially oriented* thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);

(f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as or and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and

(g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).

These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.

According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article*, i.e., the expander or catheter balloon, is *not characterized as biaxially oriented*. Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, i.e., injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII,⁴ which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon.⁵

⁴ Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

⁵ We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber*, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek*, 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made of a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, i.e., whether the catheter balloon disclosed by Schjeldahl is inherently biaxially oriented.

Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:

statements that injection blow molding without stretching will not produce a biaxially oriented article are *true* ... (emphasis supplied).

The examiner goes on, in the same sentence, to state:

but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

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upon the examiner. *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed.Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed.Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed.Cir. 1983); *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding*, 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirg v. Kemmer*, 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have *only* a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would *not* have produced a biaxially oriented balloon and would have destroyed the biaxially orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) *necessarily* means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are *inconsistent* with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

the membrane equation used to determine the tensil [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

ertainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrane equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction necessarily means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra; W.L. Gore & Associates, Inc. v. Garlock, Inc., supra; In re Oelrich, supra; In re Wilding, supra; Hansgirg v. Kemmer, supra*. Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. § 102 as anticipated by Schjeldahl is reversed.⁶

⁶ There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

The Rejection of Claims 13 through 17 under 35 U.S.C. § 103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; e.g., at least about 0.85.

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It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments.⁷ ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process.⁸ Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

⁷ Actually, according to the Final Rejection which is incorporated in the Answer,

t is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

⁸ It is apparent from our reversal of the examiner's rejection under 35 U.S.C. § 102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo*, the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. § 103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed.Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. § 103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer,⁹ we are constrained to address that issue.

⁹ The noted statement provides:

Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container*. See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees*. See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman,¹⁰ that the known processes for producing

biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill.¹¹ Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a reasonable expectation of obtaining a polymeric catheter balloon. *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed.Cir. 1988). The rejection under 35 U.S.C. § 103 is also reversed.

¹⁰ We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

¹¹ We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated

s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that

anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

REVERSED.

- End of Case -

**Page 1531
9 F.3d 1531
28 U.S.P.Q.2d 1955**

**In re Albert M.A. RIJCKAERT and Joannes A.E. Van Der Kop.
No. 93-1206.**

**United States Court of Appeals,
Federal Circuit.
Nov. 23, 1993.**

Edward W. Goodman, North American Philips Corp., of Tarrytown, NY, argued for appellant. With him on the brief was Algy Tamoshunas.

Lee E. Barrett, Associate Sol., Office of the Sol., Arlington, VA, argued for appellee. With him on the brief was Fred E. McKelvey, Sol.

Before MAYER and LOURIE, Circuit Judges, and LAY *, Senior Circuit Judge.

LOURIE, Circuit Judge.

Albert Rijckaert and Joannes van der Kop ("Rijckaert") appeal from the decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences affirming the final rejection of claims 5-12, all of the pending claims in patent application serial no. 07/345,396, as being unpatentable under 35 U.S.C. § 103 (1988). Because the references relied upon to reject

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the claims do not provide the basis for a prima facie determination that the claimed invention would have been obvious, we reverse.

BACKGROUND

The patent application at issue relates to an apparatus for recording and reproducing an electric signal on a magnetic record carrier. Independent claim 11 is drawn to a recording apparatus and it specifies a relationship between time expansion or compression and three variables, , n, and M. Claim 11 reads, in pertinent part:

11. An apparatus for recording an electric signal on a magnetic record carrier in tracks which are inclined relative to the longitudinal direction of said record carrier, comprising: ...

....

... [a] time-base correction circuit provid[ing] a time expansion or time compression of the signal blocks by a factor of $n/(180*(M+1))$, where is the wrapping angle of the record carrier around the head drum and differs from 180°, n is the number of head pairs, and M is the number of times within a specific time interval that a head pair which comes in contact with the record carrier during said time interval does not record a signal on the record carrier, said time interval being defined by those instants at which two consecutive track pairs are recorded by one or two head pairs.

Independent claim 12 is drawn to an apparatus for reproducing a recorded signal and it recites the reciprocal relationship between time compression or expansion and the three variables , and M. Dependent claims 5-10 further limit claims 11 or 12.

The Board upheld the final rejection of claims 5 and 7-12 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 4,757,392 to Awamoto in view of Driessen et al., An Experimental Digital Video Recording System, CE-32 I.E.E.E. Transactions on Consumer Electronics 3, Aug. 1986, at 362-70. The Board also upheld the final rejection of claim 6 as being unpatentable over Awamoto and Driessen in view of U.S. Patent 4,542,417 to Ohta.

DISCUSSION

We review de novo the Board's ultimate determination of obviousness. In re De Blauwe, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed.Cir.1984). Underlying factual inquiries, such as the scope and content of the prior art, differences between the prior art and the claimed invention, and level of ordinary skill in the art are reviewed for clear error. See In re Caveney, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed.Cir.1985).

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir.1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. Id. "A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." In re Bell, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed.Cir.1993) (quoting In re Rinehart, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed.Cir.1988).

All of the claims except claim 6 stand rejected under 35 U.S.C. § 103 as being obvious over Awamoto in view of Driessen. 1 Awamoto, the primary reference, discloses a signal processing circuit for a video recording and reproducing apparatus. Awamoto specifically discloses the time expansion of an input signal by a factor of two and the corresponding time compression of an output signal in a manner inverse to that of the time expansion. Further, Awamoto uses two video heads mounted on a rotary drum "of any

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of a well known video tape loading mechanism such that [the heads] follow parallel tracks skewed relative to the length of video tape." Driessen discloses a recording system using two pairs of heads mounted on piezo-ceramic actuators.

The Board concluded that the subject matter of the claims would have been obvious over Awamoto in view of Driessen, stating that "the time expansion or time compression relationship is satisfied for the expansion of two disclosed [in] Awamoto when a wrapping angle of 360° , one pair of heads and no non-recording intervals are assumed." The Board further asserted that the recognition of the claimed relationship between time expansion/compression and the three variables a, n, and M is "the mere discovery of a relationship that is applicable to [a] prior art apparatus[, and] does not [give] rise to a patentable invention." Thus, in affirming the rejection, the Board first assumed that the claim limitation at issue, the relationship between time expansion/compression and the three variables, was somehow

"inherent" in the prior art as shown by Awamoto. The Board also assumed specific values for the claimed variables in order to assert that Awamoto's device satisfies the claimed relationship.

Rijckaert argues that the examiner has not established a *prima facie* case of obviousness and that the examiner's assumptions do not constitute the disclosure of prior art. We agree. Awamoto does not disclose the wrapping angle of the record carrier around the head drum or the number of times that a head pair which comes in contact with the record carrier does not record a signal on the record carrier. Nor does Awamoto discuss the claimed relationship of the three variables to time expansion/compression. 2 Driessen, the secondary reference, is relied upon only to teach the provision of a pair of write heads having a mechanically rigid coupling to each other and does not remedy the deficiencies of Awamoto. Thus, the prior art relied upon does not disclose, suggest, or render obvious the claimed invention, either individually or when combined. 3

Awamoto does not describe the use of time expansion and compression as a means of optimally filling tracks, much less suggest that the three variables of the claims are even a factor in determining the amount of time expansion or time compression. Rather, Awamoto is concerned primarily with processing a high-quality broadcast television signal for use in conventional video machinery, and with compensating for errors introduced to such a signal by a transfer circuit. The Commissioner's assertion "that the [analysis discussed in his brief] and Awamoto demonstrate that the relationship was, in fact, well known in the art" is unavailing. While the court appreciates the Commissioner's thorough explanation of the claimed relationship in his brief, the Commissioner's brief is not prior art. The prior art is Awamoto, and it does not indicate that the relationship is well known in the art, nor does it suggest the claimed relationship. See *In re Yates*, 663 F.2d 1054, 211 USPQ 1149, 1151 (CCPA 1981) (when the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference).

To support the Board's affirmance of the rejection, the Commissioner points out that in the recording art, the exact matching of signal time to recording time is an optimal

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condition, and that this condition would be met by fulfilling the claimed relationship. While the condition described may be an optimal one, it is not "inherent" in Awamoto. Nor are the means to achieve this optimal condition disclosed by Awamoto, explicitly or implicitly. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency]." *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981) (citations omitted) (emphasis added). "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. See *In re Newell*, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed.Cir.1989).

Rijckaert also argues that the rejection of dependent claim 6 as being obvious over Awamoto and Driessen in view of Ohta is improper. Ohta discloses an apparatus for compensating for signal loss in a single-head video recorder using a time compression factor of 3/5 (a signal of time period 5t/4 is compressed into a track of time period 3t/4) so that a signal is recorded completely during the time period that it takes the recording head to scan the magnetic tape. Regarding the Ohta patent, the examiner stated, "Ohta was only relied upon to support the idea that other compression factors are used in the prior art...." 4 The relationship between the time expansion/compression and the three variables recited in the claims from which claim 6 depends, which is absent in the combination of Awamoto and Driessen, is not

supplied by Ohta. Thus, we agree that the rejection of claim 6 under § 103 is improper for the reasons set forth above with respect to the other claims.

While the Commissioner criticizes Rijckaert's arguments regarding the § 103 rejections, the burden to rebut a rejection of obviousness does not arise until a *prima facie* case has been established. In the case before us, it was not.

CONCLUSION

The decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences affirming the final rejection is reversed.

REVERSED.

* Honorable Donald P. Lay, Senior Circuit Judge, United States Court of Appeals for the Eighth Circuit, sitting by designation.

1 The claims stand or fall together since no separate argument for patentability has been made for each claim.

2 The Commissioner admits that other limitations recited in claims 11 and 12 are not found in Awamoto; however, those limitations were not argued before the Board or this court. Thus, we agree with the Commissioner that those limitations are not at issue here.

3 The Board also noted that the claims are not "specific" in that they claim the three variables as a "factor" of the expansion or compression time. The Board stated, "claims 11 and 12 fail to say which of expansion time or compression time is factored by the variables, how or when one of the two times is selected based on the variables or how each of the two times is related to the variables." The Board further stated, "the relationship is probably satisfied by any prior art video tape recording and reproducing apparatus that otherwise satisfies the remaining requirements of the claims at bar." While the Board's position implies a possible rejection based upon 35 U.S.C. § 112, this issue is not before us. In any event, the statement that the relationship is "probably satisfied" by the prior art is speculative and therefore does not establish a *prima facie* case of unpatentability.

4 The Board did not specifically address the rejection of claim 6; therefore, claim 6 was considered to be affirmed for the reasons stated by the examiner. See 37 C.F.R. § 1.196(a) (1993).

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169 F.3d 743
49 U.S.P.Q.2d 1949
In re Anthony J. ROBERTSON and Charles L. Scripps.
No. 98-1270.
United States Court of Appeals,
Federal Circuit.
Feb. 25, 1999.

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Kenneth R. Adamo, Jones, Day, Reavis & Pogue, of Cleveland, Ohio, argued for appellant. With him on the brief were Calvin P. Griffith, and Gregory A. Castanias, of Washington, DC. Of counsel on the brief was Steven W. Miller, The Proctor & Gamble Company, of Cincinnati, Ohio.

Linda Moncys Isacson, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With her on the brief were Albin F. Drost, Acting Solicitor, and John M. Whealan, Associate Solicitor.

Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

Opinion for the court filed by Senior Circuit Judge FRIEDMAN, in which Circuit Judge PAULINE NEWMAN joins. Concurring opinion filed by Circuit Judge RADER.

FRIEDMAN, Senior Circuit Judge:

This appeal challenges the decision of the Board of Patent Appeals and Interferences (Board) that claim 76 in the appellants' patent application was anticipated by and obvious over United States Patent No. 4,895,569 (the Wilson patent). We reverse.

I

Both claim 76 and Wilson involve fastening and disposal systems for diapers. In both, the body of the diaper features a small front and a larger rear section. The outer edges of those sections are attached at the wearer's waist in the hip area. Once the diaper is soiled and then removed, the smaller front section is rolled up into the larger rear section and secured in this rolled-up configuration by fasteners.

The appellants' application is for "an improved mechanical fastening system for ... disposable absorbent articles [i.e., diapers] that provides convenient disposal of the absorbent article." Claim 76 covers:

[A] mechanical fastening system for forming side closures ... comprising

a closure member ... comprising a first mechanical fastening means for forming a closure, said first mechanical fastening means comprising a first fastening element;

a landing member ... comprising a second mechanical fastening means for forming a closure with said first mechanical fastening means, said second mechanical fastening means comprising a second fastening element mechanically engageable with said first element; and

disposal means for allowing the absorbent article to be secured in a disposal configuration after use, said disposal means comprising a third mechanical fastening means for securing the absorbent article in the disposal configuration, said third mechanical fastening means comprising a third fastening element mechanically engageable with said first fastening element ...

Claim 76 thus provides for two mechanical fastening means to attach the diaper to the wearer and a third such means for securing the diaper for disposal.

The Wilson patent discloses two snap elements on fastening strips attached to the outer edges of the front and rear hip sections of the garment. The fastening strips may also include "secondary load-bearing closure means"--additional fasteners to secure the garment; they may be identical to the snaps.

Wilson also states:

[D]isposal of the soiled garment upon removal from the body is easily accomplished by folding the front panel ... inwardly and then fastening the rear pair of mating fastener members ... to one another, thus neatly bundling the garment into a closed compact package for disposal.

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In other words, Wilson does not provide a separate fastening means to be used in disposing of the diaper. Instead, it suggests that disposal of the used diaper may be "easily accomplished" by rolling it up and employing the same fasteners used to attach the diaper to the wearer to form "a closed compact package for disposal."

In holding that the invention claim 76 covers was anticipated by Wilson, the Board did not hold that Wilson set forth a third fastening means. Instead, it found that Wilson anticipated claim 76 "under principles of inherency." Applying the language of claim 76 to the operation of Wilson, it concluded that "an artisan would readily understand the disposable absorbent garment of Wilson ... as being inherently capable of [making the secondary load-bearing closure means] (third fastening element) mechanically engageable with [the other snap fasteners on the fastening strip] (first fastening element)"--i.e., using the secondary closure not with its mate, but with one of the primary snap fasteners. The Board summarily affirmed the examiner's alternative ruling that claim 76 would have been obvious in light of Wilson because "claim 76 lacks novelty."

II

Anticipation under 35 U.S.C. § 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed.Cir.1987).

A. The Wilson patent does not expressly include a third fastening means for disposal of the diaper, as claim 76 requires. That means is separate from and in addition to the other mechanical fastening means and performs a different function than they do. Indeed, Wilson merely suggests that the diaper may be closed for disposal by using the same fastening means that are used for initially attaching the diaper to the body.

If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic

evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed.Cir.1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1269, 948 F.2d 1264, 20 U.S.P.Q.2d at 1749 (quoting In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A.1981)).

In finding anticipation by inherency, the Board ignored the foregoing critical principles. The Board made no attempt to show that the fastening mechanisms of Wilson that were used to attach the diaper to the wearer also "necessarily" disclosed the third separate fastening mechanism of claim 76 used to close the diaper for disposal, or that an artisan of ordinary skill would so recognize. It cited no extrinsic evidence so indicating.

Instead, the Board ruled that one of the fastening means for attaching the diaper to the wearer also could operate as a third fastening means to close the diaper for disposal and that Wilson therefore inherently contained all the elements of claim 76. In doing so, the Board failed to recognize that the third mechanical fastening means in claim 76, used to secure the diaper for disposal, was separate from and independent of the two other mechanical means used to attach the diaper to the person. The Board's theory that these two fastening devices in Wilson were capable of being intermingled to perform the same function as the third and first fastening elements in claim 76 is insufficient to show that the latter device was inherent in Wilson. Indeed, the Board's analysis rests upon the very kind of probability or possibility--the odd use of fasteners with other than their mates--that this court has pointed out is insufficient to establish inherency.

III

The Board's entire discussion of obviousness was as follows:

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The rejection of claim 76 under 35 USC § 103

We sustain the rejection of claim 76 under 35 USC § 103.

Above, we found that claim 76 lacks novelty. Lack of novelty is the ultimate of obviousness. See In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982). Thus, claim 76 is appropriately rejected under 35 USC § 103 as being unpatentable.

The "lack of novelty" upon which the Board based its conclusion of obviousness, however, was its finding of anticipation. Our rejection of that finding eliminates the sole basis of the Board's obviousness determination, which therefore cannot stand. See In re Adams, 53 C.C.P.A. 1433, 364 F.2d 473, 480, 150 U.S.P.Q. 646, 651 (1966).

In his brief the Commissioner argues:

Moreover, even if this court interprets claim 76 to require two separate fasteners to perform the closure and disposal functions, it would have been well within the knowledge of one of ordinary skill in the art to take Wilson's one fastener and make it into two separate fasteners. See [In re J Graves, 69 F.3d [1147,] 1152, 36 USPQ2d [1697,] 1701 [(Fed.Cir.1995)] (When evaluating a reference, it is appropriate to

consider the knowledge of a skilled artisan in combination with the teaching of the reference.). Accordingly, claim 76 would have been obvious to one of ordinary skill in the art, and the rejection should be affirmed by this Court.

That, of course, was not the ground on which the Board based its obviousness ruling. We decline to consider counsel's newly-minted theory as an alternative ground for upholding the agency's decision. See *In re Soni*, 54 F.3d 746, 751, 34 U.S.P.Q.2d 1684, 1688 (Fed.Cir.1995) (citing *In re DeBlauwe*, 736 F.2d 699, 705 n. 7, 222 U.S.P.Q. 191, 196 n. 7 (Fed.Cir.1984)). The Board's obviousness ruling cannot be sustained on the ground the Board gave.

CONCLUSION

The decision of the Board of Patent Appeals and Interferences affirming the examiner's rejection of claim 76 as anticipated by and obvious over the Wilson patent is

REVERSED.

RADER, Circuit Judge, concurring.

Robertson asserts that the prior art Wilson patent does not teach three elements of claim 76: a "third mechanical fastening means," a disposal means on the "outside surface" of the body portion, and end regions that are "in an overlapping configuration when worn." In reversing the Board, this court relies solely on the purported failure of Wilson to teach the third fastening means. Because I believe Wilson teaches such a means, but does not teach the other two limitations at issue, I concur.

In its analysis, this court assumes without discussion that the claimed "third mechanical fastening means" covers a separate third mechanical fastening means. This issue is key, for if the claim does not require a separate third fastening means, but instead allows the first fastening means to also serve as the third, then the prior art Wilson patent clearly teaches that element of the claim. For two reasons, this claim does not, to my eyes, require a separate third fastening means. First, the claim does not specifically recite a separate third fastening means. Second, because the claim is in means-plus-function form, this court consults the specification to identify structure. The specification explicitly teaches that the first and third fastening elements can be the same so long as they are complementary, as they are in Wilson. Accordingly, I agree with the Board that Wilson teaches the claimed "third fastening element."

Wilson does not, however, teach either of the other two claim limitations at issue. As to the disposal means on the "outside surface" of the body portion, Wilson's figs. 12 and 13a-d show the disposal means on the inside of the body portion. As to the end regions that are "in an overlapping configuration when worn," Wilson explicitly teaches that the end regions should abut, not overlap, when worn. To overcome these teachings, the Board relied on the following statement in Wilson: "Further, the fastener members

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need not be previously mounted on a separate strip as shown then bonded ... to the stretchable outer cover.... Multi-component snaps are available which may be applied directly to a stretchable outer cover material...." Col. 7, l. 65 to col. 8, l. 3. The Board opined that applying snaps directly to the outer cover would result in both a disposal means on the "outside surface" and end regions "in an overlapping configuration when worn." Simply put, the Board has put more weight on this teaching than it can bear. It is far from clear what effect applying the snaps directly to the outer cover will have on the Wilson diaper

configuration, let alone that it will result in a configuration satisfying the claim elements at issue. Accordingly, because I believe that the Board clearly erred in this interpretation of Wilson, I would reverse on this ground.

Source: USPQ, 1st Series (1929 - 1986) > U.S. Court of Customs and Patent Appeals > In re ROYKA AND MARTIN, 180 USPQ 580 (C.C.P.A. 1974)

In re ROYKA AND MARTIN, 180 USPQ 580 (C.C.P.A. 1974)

180 USPQ 580
In re ROYKA AND MARTIN
U.S. Court of Customs and Patent Appeals
No. 9092
Decided February 7, 1974
490 F2d 981

Headnotes

PATENTS

[1] Patentability — Anticipation — Combining references (► 51.205)

To support anticipation rejection, all elements of claim must be found in reference.

[2] Construction of specification and claims — Broad or narrow — In general (► 22.101)

Construction of specification and claims — By specification and drawings — In general (► 22.251)

Claims are not read in a vacuum; while they are given broadest reasonable interpretation during prosecution, their terms still must be given meaning called for by specification of which they form a part.

[3] Patentability — Anticipation — In general (► 51.201)

Anticipation requires a finding that claimed invention be disclosed; it is not enough to say that applicants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper.

[4] Patentability — Subject matter for patent monopoly — Printed matter (► 51.611)

It is not a valid reason for rejection that claim is merely a printed matter variation of design of reference; printed matter may very well constitute structural limitations upon which patentability can be predicated.

Particular Patents

Particular patents—Answer System

Royka and Martin, Responsive Answer System, claims 28 and 30 to 36 of application allowed.

Case History and Disposition

Appeal from Board of Appeals of the Patent Office.

Application for patent of Stephen F. Royka and Robert G. Martin, Serial No. 648,701, filed June 26, 1967; Patent Office Group 336. From decision rejecting claims 28 and 30 to 36, applicants appeal. Reversed.

Attorneys

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MICHAEL H. SHANAHAN, Fairport, N. Y. (THOMAS M. WEBSTER, Fairport, N. Y., and BORIS HASKELL and PARIS, HASKELL & LEVINE, both of Arlington, Va., of counsel) for appellants.

JOSEPH F. NAKAMURA (FRED W. SHERLING of counsel) for Commissioner of Patents.

Judge

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE, and MILLER, Associate Judges.

Opinion Text

Opinion By:

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 28 and 30-36 of application serial No. 648,701, filed June 26, 1967, entitled "Responsive Answer System." We reverse.

The Invention

The appealed claims are directed to a device in the nature of an answer sheet for use in self-instruction and testing. The answer sheet may be associated with questions or separate therefrom. The essential features of the invention are that there are printed on the answer sheet in "response areas" meaningful information in permanent printing and confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer. The following figures from the drawings are illustrative:

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA at 1-800-372-1033.

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA at 1-800-372-1033.

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Fig. 1A shows two response areas to a given question before any removing action by the student has taken place and Fig. 1B shows the permanent information remaining in each after erasure of the removable information. Of course, if the student makes an initial choice of area A, showing up "YES" or some other indication of a correct answer, he will not need to proceed further and erase the B area. In a modified form of the invention, a wrong selection, plus erasure, may expose, instead of or in addition to a statement that the answer is wrong, a number or other reference to further material which is to be studied.

A preferred method of printing the permanent meaningful information and the removable confusing information is by that type of xerography in which a fusible toner is used, the permanence of the printing depending on the extent to which the toner image is "fixed" or fused by heat. By successive printings of the two kinds of information with fixing to different degrees, one image can be made permanent and the other made subject to easy removal, both images retaining such similarity of appearance that the user of the answer sheet cannot tell them apart.

Claim 28 is the principal claim, all others being dependent thereon, and reads as follows:

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28. A device for selectively indicating information comprising
a support having response areas for presenting information for selection,
permanent printing indicative of meaningful information permanently fixed to said support within a
response area, and
removable printing indicative of confusing information removably fixed to said support within a
response area,
said meaningful and confusing information being substantially legible even when said permanent
and removable printing are fixed over one another on said support,
said permanent and removable printing being substantially similar such that an observer cannot
determine which information is permanent and which is removable
whereby the information within a response area is selected by attempting to remove the printing
therein with the failure to remove printing identifying meaningful information.

Claims 30-36 add limitations which need not be considered except for noting that claims 33 and 34 alone specify the use of a xerographic toner, for which reason they were rejected on a different ground from the other claims.

The Rejection

The following references were relied on:

Reid et al. (Reid) 356,695 Jan. 25, 1887

Bernstein et al. (Bernstein) 3,055,117 Sep. 25, 1962

Lein et al. (Lein) 3,364,857 Jan. 23, 1968 (filed Feb. 2, 1966)

Claims 28, 30, 31, and 32 were rejected as anticipated under 35 U.S.C. 102 by Bernstein; claims 28, 31, 32, 35, and 36 were rejected as anticipated under § 102 by Reid; and claims 33 and 34 were rejected under 35 U.S.C. 103 for obviousness, on either Bernstein or Reid in view of Lein. These were the examiner's rejections and the board *affirmed* them, adhering to its decision *on reconsideration*.

Bernstein discloses an answer sheet in which printed information representing a response is "temporarily concealed from the observer" and he discloses a number of different ways of effectively concealing the response. His specification states:

The objects of the invention are accomplished by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable and thus conceal the presence, absence, nature or position of the response from the participant. This may be effectuated by careful attention being paid to a number of factors including the design, color and position of the hiding or confusing media.

Fig. 1 of Bernstein's drawings illustrates some of his concealing means:

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA at 1-800-372-1033.

The following is the written description:

Referring now to the drawing, FIG. 1 illustrates some of the many optically confusing patterns which may be positioned between the printed structure to be concealed and the point of observation. Column 11 shows the information which is to be concealed. This information is repeated in columns 12 through 16 but in each case is concealed by a pattern in accordance with the present invention. Column 12 utilizes a pattern comprising an alphabetical maze in both line and half tone screen. Column 13 utilizes a pattern comprising an absorbing field having a plurality of irregular dot-like interstices. Column 14 utilizes a pattern comprising a maze of plus signs combined with dots. Columns 15 and 16 illustrate irregular and non-repetitious patterns.

Bernstein says that if at least 50% of the response is actually covered by the opaque portions of the confusion pattern, complete concealment is obtained. He also says that added means of concealment may be used, such as scoring and embossing and perforating the paper in order to scatter the light or let it shine through.

Reid is entitled "Transformation Picture and Print." The invention is said to be useful for advertisements, Christmas cards, birthday cards, valentines, and the like and as a source of amusement and instruction for children. It consists of a picture or print, part of which is permanently printed and part of which is removable from the paper on which it is printed. For the latter various soluble undercoatings or inks are described. If the picture is washed with a solvent, which may be water, the removable part disappears and the pictorial and/or typographic matter changes. The invention is illustrated by a typical nineteenth century temperance propaganda piece depicting the evils of drink. In the finished picture there are three scenes from left to right: Scene 1, the innocent child leads her father home from the pub; Scene 2, Father sits slumped in the kitchen chair with his bottle beside him, the family wash hanging above his head, this picture being entitled "The Effects of Drink"; Scene 3, Mother stands in front of a sign reading "Pawn Shop." Across the bottom of the picture is a legend which says "Wash the above and see what water will do." Fig. II shows the result of washing with water: Scene 1, a handsome young man and his happy daughter stroll on the street; Scene 2, Father sits erect in a well-appointed room at a cloth-covered table, apparently having a cup of tea, obviously a gentleman; Scene 3, Mother beams from the sideline and the Pawn Shop sign has vanished. Two new subscriptions appear and the words "The" and "Drink" have disappeared, the resultant being a new picture title reading "The Beneficial Effects of Temperance." "The Beneficial" and "Temperance" were covered by some soluble opaque in the original picture. No doubt the overall effect is instruction. Perhaps there was amusement in bringing about the transformation.

Lein relates to xerography and is relied on only for its disclosure of the removability of partially fused toner and the permanence of fully fused toner.

Opinion

[1] As to the § 102 anticipation rejections, it will suffice to consider independent claim 28. If it is not fully met by Reid or Bernstein, neither are the more limited dependent claims. It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of *legible* meaningful and *legible* confusing *information* simultaneously, between which the user of the device may make a selection before he undertakes to remove any of the information from the response area selected by him. The element we find most clearly missing, contrary to the reasoning of the examiner and the board, is the *legible* confusing *information*. The Patent Office proposes to read this limitation on Bernstein's confusion patterns which are nothing but meaningless obscuring screens, conveying no information and providing the user with no basis for making a *selection*, as called for by claim 28. In appellants' device the *legible* confusing information—i.e., the wrong answers—are *legible* in the sense that they can be read as intelligible words, not merely a jumble of type serving to obscure the words of the wrong answers.

Appellants were fully aware of Bernstein and discussed its disclosures in their specification, distinguishing from this and other prior art, saying, in part:

The inventive concept hereof confuses not by physical blocking as taught by the prior art, but by compounding, associating (including disarranging) permanent information with confusing information, usually at least some of which is similar in character to the permanent information as to render it impossible to tell which is permanent and which is removable confusing information. In the invention, generally no attempt is made to designedly physically cover the permanent information, but to confuse it beyond interpretation by the presentation of extraneous, removable, confusing information.

- [2] Claims are not to be read in a vacuum and while it is true they are to be given the broadest reasonable interpretation during

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prosecution, their terms still have to be given the meaning called for by the specification of which they form a part. We cannot read the terms "legible" and "information" on Bernstein's confusion patterns, as did the examiner and the board. They are not "legible," as appellants use the term, and they convey no information.

As to anticipation by Reid, we find neither appellants' basic concept nor the substance of claim 28 to be disclosed. Apparently the solicitor could find little to support the rejection in Reid for all he says in his brief—so far as claim 28 is concerned—is:

Reid discloses a sheet which may be used for instruction and which may have a removable design partly covering a fixed design * * *. Therefore, the disclosure of the reference encompasses the arrangement wherein a removable design covers a fixed design with both designs being substantially legible.

- [3] But claim 28 does not call for an arrangement wherein a removable design covers a fixed design. It calls for response areas, which Reid does not have, containing meaningful information in permanent printing together with removable printing conveying confusing information, both legible at the same time, between which a "selection" can be made. The only choice offered to the user by Reid is to follow the instruction to wash the whole visible picture with water or other solvent, thus removing the overprinting, to discover what the permanent picture is. The Patent Office attempt to read claim 28 on this reference is a tour de force. We hold that Reid does not anticipate for failure to meet the limitations of claim 28 to "response areas," to the presentation of two categories of information (meaningful-permanent and removable-confusing) within such areas, and the possibility of selection. Anticipation requires a finding that the claimed invention be disclosed. It is not enough to say that appellants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper, as did the solicitor.

The dependent claims rejected with claim 28, as anticipated under § 102, are not anticipated since claim 28 is not anticipated. Some of them merely add features which are disclosed by the references and some do not. Insofar as they do not, they further negative anticipation. The examiner recognized this fact as to claims 33 and 34, which are limited to xerography, and therefore did not reject them under § 102. Similarly, he did not reject claim 30 on Reid or claims 35 and 36 on Bernstein. We find that claims 35 and 36 contain limitations which additionally distinguish from Reid. We have already noted that Reid has no "response areas" as required by claim 28 and so Reid does not disclose the structure of claim 35 which additionally requires both the correct and incorrect answers to appear within the same response area.

- [4] As to claim 36, the examiner said it "is merely a printed matter variation of the design of the reference," Reid. This is not a valid reason for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated. We have commented on this matter in *In re Jones*, 54 CCPA 1218, 373 F.2d 1007, 153 USPQ 77 (1967); and *In re Miller*, 57 CCPA 809, 418 F.2d 1392,

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164 USPQ 46 (1969), and will not repeat ourselves. The limitations of claim 36 are not remotely suggested by Reid.

There remains the § 103 rejection of claims 33 and 34. Do they, taken together with all of the limitations of claim 28 from which they depend, define obvious subject matter? The difference between claim 28 and these two dependent claims is that they add the limitations to xerography. If Bernstein and Reid showed the claimed invention except for xerography, the addition of the Lein reference would make the subject matter of the claims obvious. But that is not the situation here. Adding the knowledge of xerographic technology to Bernstein or Reid still does not make the invention of claims 33 and 34 obvious for the same reasons we have given above in discussing anticipation. The essence of appellants' invention, as set forth in claim 28, is still missing notwithstanding the addition of the Lein reference and we see nothing in the combinations of references which would have made the invention obvious to one of ordinary skill in the art at the time it was made. We will, therefore, reverse this rejection.

The decision of the board is reversed .

- End of Case -

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814 F.2d 628

2 U.S.P.Q.2d 1051

**VERDEGAAL BROTHERS, INC., William Verdegaal, George
Verdegaal, Appellees,**

v.

**UNION OIL COMPANY OF CALIFORNIA, Brea Agricultural Services,
Inc., Appellants.**

Appeal No. 86-1258.

**United States Court of Appeals,
Federal Circuit.
March 12, 1987.**

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Andrew J. Belansky, Christie, Parker & Hale, Pasadena, Cal., argued for appellants.

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With him on the brief was David A. Dillard.

John P. Sutton, Limbach, Limbach & Sutton, San Francisco, Cal., argued for appellees. With him on the brief was Michael E. Dergosits.

Before MARKEY, Chief Judge, and DAVIS and NIES, Circuit Judges.

NIES, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. 4,310,343 ('343), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

BACKGROUND

The General Technology

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

The Process of the '343 Patent

The process disclosed in the '343 patent involves the chemical reaction between urea and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a previously-made batch of liquid fertilizer--known as a "heel"--can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:
 - a. providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
 - b. adding water to the heat sink in an amount not greater than 15% of the end product,
 - c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
 - d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.
2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

Procedural History

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its '343 patent. Union Oil defended on the grounds of noninfringement and patent invalidity under 35 U.S.C. Secs. 102, 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the '343 patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal.

Having unsuccessfully moved for a directed verdict under Fed.R.Civ.P. 50(a), Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the '343 patent were invalid

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under sections 102 and 103. The district court denied the motion without opinion.

II

ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the '343 patent?

III

Fastcase

Standard of Review

When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1512-13, 220 USPQ 929, 936 (Fed.Cir.), cert. denied, 469 U.S. 871, 105 S.Ct. 220, 83 L.Ed.2d 150 (1984); Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed.Cir.1983). A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. Railroad Dynamics, 727 F.2d at 1513, 220 USPQ at 936; Connell, 722 F.2d at 1546, 220 USPQ at 197.

To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. See Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed.Cir.), cert. denied, 469 U.S. 857, 105 S.Ct. 187, 83 L.Ed.2d 120 (1984); Railroad Dynamics, 727 F.2d at 1512, 220 USPQ at 936. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 59 S.Ct. 206, 216, 83 L.Ed. 126 (1938); Perkin-Elmer, 732 F.2d at 893, 221 USPQ at 673; SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 371 n. 10, 218 USPQ 678, 684 n. 10 (Fed.Cir.1983). A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed.Cir.1984).

Our precedent holds that the presumption of validity afforded a U.S. patent by 35 U.S.C. Sec. 282 requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed.Cir.), cert. denied, 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984). Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims in issue were invalid. See Perkin-Elmer, 732 F.2d at 893, 221 USPQ at 673; Railroad Dynamics, 727 F.2d at 1511, 220 USPQ at 935.

Anticipation

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed.Cir.1984); Connell, 722 F.2d at 1548, 220 USPQ at 198; Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983), cert. denied, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). Union Oil asserts that the subject claims of the '343 patent

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are anticipated under 35 U.S.C. Sec. 102(e) 1 by the teachings found in the original application for U.S. Patent No. 4,315,763 to Stoller, which the jury was instructed was prior art.

From the jury's verdict of patent validity, we must presume that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. See Perkin-Elmer, 732 F.2d at 893, 221 USPQ at 673; Railroad Dynamics, 727 F.2d at 1516, 220 USPQ at 939. Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30-0-0-10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount of at least 10% of the product. Verdegaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled fertilizer. 2

The Stoller specification, beginning at column 7, line 30, discloses:

Once a batch of liquid product has been made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.

This portion of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaal presented no evidence to the contrary.

Verdegaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added slowly, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaal to rely on that distinction. See SSIH, 718 F.2d at 378, 218 USPQ at 689. It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.

Verdegaal next argues that the testimony of Union Oil's experts with respect to what Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product.

Verdegaal raises several variations of an argument, all of which focus on the

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failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaal's own expert, Dr. Bahme, admitted that Stoller discussed the problem of high temperature caused by the

exothermic reaction, and that the heel could function as a heat sink. 3 In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. See *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.

On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief:

Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under 35 U.S.C. Secs. 102(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art.... This conclusion finds support in *In re Wertheim*, 646 F.2d 527 (CCPA 1981), and 1 Chisum on Patents Sec. 3.07.

Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the '343 patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was not prior art, but rather, stated that he did not know whether it was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:

Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?

A. (Prof. Chisum): I don't know that it is, no.

We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art. 4 Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered prior art. See Fed.R.Civ.P. 51; *Weinar v. Rollform Inc.*, 744 F.2d 797, 808, 223 USPQ 369, 375 (Fed.Cir.1984), cert. denied, 470 U.S. 1084, 105 S.Ct. 1844, 85 L.Ed.2d 143 (1985); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed.Cir.), cert. denied, 469 U.S. 1038, 105 S.Ct. 516, 83 L.Ed.2d 405 (1984). 5

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After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing evidence and that no reasonable juror could find otherwise. Consequently, the jury's verdict on validity is unsupported by substantial evidence and cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

Conclusion

Fastcase

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil. 6 In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the '343 patent as valid under section 102(e) and infringed.

REVERSED.

1 Section 102(e) provides:

A person shall be entitled to a patent unless--

....

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent....

2 Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

3 There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

4 The jury instruction read:

Stoller filed two patent applications--an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

5 Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:

[B]ut I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

6 It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any issue which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. See Railroad Dynamics, 727 F.2d at 1511, 220 USPQ at 934.

proportionate share of the administrative costs of the Patent and Trademark Office.

(d) The Director may refund any fee paid by mistake or any amount paid in excess of that required.

(e) The Secretary of Commerce shall, on the day each year on which the President submits the annual budget to the Congress, provide to the Committees on the Judiciary of the Senate and the House of Representatives:

(1) a list of patent and trademark fee collections by the Patent and Trademark Office during the preceding fiscal year;

(2) a list of activities of the Patent and Trademark Office during the preceding fiscal year which were supported by patent fee expenditures, trademark fee expenditures, and appropriations;

(3) budget plans for significant programs, projects, and activities of the Office, including out-year funding estimates;

(4) any proposed disposition of surplus fees by the Office; and

(5) such other information as the committees consider necessary.

(Amended Nov. 14, 1975, Public Law 94-131, sec. 4, 89 Stat. 690; Dec. 12, 1980, Public Law 96-517, sec. 3, 94 Stat. 3018; Aug. 27, 1982, Public Law 97-247, sec. 3(g), 96 Stat. 319; Sept. 13, 1982, Public Law 97-258, sec. 3(i), 96 Stat. 1065.)

(Subsection (c) amended Dec. 10, 1991, Public Law 102-204, sec. 5(e), 105 Stat. 1640.)

(Subsection (e) added Dec. 10, 1991, Public Law 102-204, sec. 4, 105 Stat. 1637.)

(Subsection (c) revised Nov. 10, 1998, Public Law 105-358, sec. 4, 112 Stat. 3274.)

(Amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-555, 582 (S. 1948 secs. 4205 and 4732(a)(10)(A))).

PART II — PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

CHAPTER 10 — PATENTABILITY OF INVENTIONS

Sec.

100 Definitions.

101 Inventions patentable.

102 Conditions for patentability; novelty and loss of right to patent.

103 Conditions for patentability; non-obvious subject matter.

104 Invention made abroad.

105 Inventions in outer space.

35 U.S.C. 100 Definitions.

When used in this title unless the context otherwise indicates -

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.

(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

(e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 or inter partes reexamination under section 311 who is not the patent owner.

(Subsection (e) added Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-567 (S. 1948 sec. 4603).)

35 U.S.C. 101 Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

(Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; Nov. 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691.)

(Subsection (e) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-565 (S. 1948 sec. 4505).)

(Subsection (g) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-590 (S. 1948 sec. 4806).)

(Subsection (e) amended Nov. 2, 2002, Public Law 107-273, sec. 13205, 116 Stat. 1903.)

35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)—

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means—

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

owner and any third party requester, will be notified if claims are rejected, objections or requirements made, or decisions favorable to patentability are made, in the same manner as after the first examination (§ 1.104). Applicant or patent owner may reply to such Office action in the same manner provided in § 1.111 or § 1.945, with or without amendment, unless such Office action indicates that it is made final (§ 1.113) or an appeal (§ 41.31 of this title) has been taken (§ 1.116), or in an inter partes reexamination, that it is an action closing prosecution (§ 1.949) or a right of appeal notice (§ 1.953).

[46 FR 29182, May 29, 1981; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; revised, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000; revised, 65 FR 76756, Dec. 7, 2000, effective Feb. 5, 2001; revised, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.113 Final rejection or action.

(a) On the second or any subsequent examination or consideration by the examiner the rejection or other action may be made final, whereupon applicant's, or for *ex parte* reexaminations filed under § 1.510, patent owner's reply is limited to appeal in the case of rejection of any claim (§ 41.31 of this title), or to amendment as specified in § 1.114 or § 1.116. Petition may be taken to the Director in the case of objections or requirements not involved in the rejection of any claim (§ 1.181). Reply to a final rejection or action must comply with § 1.114 or paragraph (c) of this section. For final actions in an inter partes reexamination filed under § 1.913, see § 1.953.

(b) In making such final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof.

(c) Reply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the reply to a final rejection or action must comply with any requirements or objections as to form.

[24 FR 10332, Dec. 22, 1959; 46 FR 29182, May 29, 1981; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; revised, 65 FR 14865, Mar. 20, 2000, effective May 29, 2000 (adopted as final, 65 FR 50092, Aug. 16, 2000); para. (a) revised, 65 FR 76756, Dec. 7, 2000, effective Feb. 5, 2001; para. (a) revised, 68 FR 14332, Mar. 25,

2003, effective May 1, 2003; para. (a) revised, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.114 Request for continued examination.

(a) If prosecution in an application is closed, an applicant may request continued examination of the application by filing a submission and the fee set forth in § 1.17(e) prior to the earliest of:

- (1) Payment of the issue fee, unless a petition under § 1.313 is granted;
- (2) Abandonment of the application; or
- (3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.

(b) Prosecution in an application is closed as used in this section means that the application is under appeal, or that the last Office action is a final action (§ 1.113), a notice of allowance (§ 1.311), or an action that otherwise closes prosecution in the application.

(c) A submission as used in this section includes, but is not limited to, an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability. If reply to an Office action under 35 U.S.C. 132 is outstanding, the submission must meet the reply requirements of § 1.111.

(d) If an applicant timely files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will be entered and considered. If an applicant files a request for continued examination under this section after appeal, but prior to a decision on the appeal, it will be treated as a request to withdraw the appeal and to reopen prosecution of the application before the examiner. An appeal brief (§ 41.37 of this title) or a reply brief (§ 41.41 of this title), or related papers, will not be considered a submission under this section.

(e) The provisions of this section do not apply to:

- (1) A provisional application;
- (2) An application for a utility or plant patent filed under 35 U.S.C. 111(a) before June 8, 1995;
- (3) An international application filed under 35 U.S.C. 363 before June 8, 1995;

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

§ 1.191 Appeal to Board of Patent Appeals and Interferences.

Appeals to the Board of Patent Appeals and Interferences under 35 U.S.C. 134(a) and (b) are conducted according to part 41 of this title.

[46 FR 29183, May 29, 1981; para. (a), 47 FR 41278, Sept. 17, 1982, effective Oct. 1, 1982; para. (d), 49 FR 555, Jan. 4, 1984, effective Apr. 1, 1984; 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; paras. (b) and (d) amended, para. (e) added, 54 FR 29553, July 13, 1989, effective Aug. 20, 1989; para. (d) revised, 58 FR 54504, Oct. 22, 1993, effective Jan. 3, 1994; paras. (a) and (b) revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; para. (a) revised, 65 FR 76756, Dec. 7, 2000, effective Feb. 5, 2001; para. (e) revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003; para. (a) revised, 68 FR 70996, Dec. 22, 2003, effective Jan. 21, 2004; revised, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.192 [Reserved]

[36 FR 5850, Mar. 30, 1971; para. (a), 47 FR 41278, Sept. 17, 1982, effective Oct. 1, 1982; para. (a), 49 FR 556, Jan. 4, 1984, effective Apr. 1, 1984; 53 FR 23734, June 23, 1988, effective Sept. 12, 1988; para. (a), (c), and (d) revised, 58 FR 54504, Oct. 22, 1993, effective Jan. 3, 1994; paras. (a)-(c) revised, 60 FR 14488, Mar 17, 1995, effective Apr. 21, 1995; para. (a) revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; removed and reserved, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.193 [Reserved]

[24 FR 10332, Dec. 22, 1959; 34 FR 18858, Nov. 26, 1969; para. (c), 47 FR 21752, May 19, 1982, added effective July 1, 1982; para. (b), 50 FR 9382, Mar. 7, 1985, effective May 8, 1985; 53 FR 23735, June 23, 1988, effective Sept. 12, 1988; para. (c) deleted, 57 FR 2021, Jan. 17, 1992, effective Mar. 16, 1992; para. (b) revised, 58 FR 54504, Oct. 22, 1993, effective Jan. 3, 1994; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; para. (b)(1) revised, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000; para. (a)(1) revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003; removed and reserved, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.194 [Reserved]

[42 FR 5595, Jan. 28, 1977; paras. (b) & (c), 47 FR 41278, Sept. 17, 1982, effective Oct. 1, 1982; para. (a), 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; para. (b) revised 53 FR 23735, June 23, 1988, effective Sept. 12, 1988; para. (b) revised, 58 FR 54504, Oct. 22, 1993, effective Jan. 3, 1994; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; removed and reserved, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.195 [Reserved]

[34 FR 18858, Nov. 26, 1969; removed and reserved, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.196 [Reserved]

[24 FR 10332, Dec. 12, 1959; 49 FR 29183, May 29, 1981; 49 FR 48416, Dec. 12, 1984, effective Feb. 12, 1985; para. (b) revised, 53 FR 23735, June 23, 1988, effective Sept. 12, 1988; paras. (a), (b) & (d) amended, paras. (e) & (f) added, 54 FR 29552, July 13, 1989, effective Aug. 20, 1989; para. (f) revised, 58 FR 54504, Oct. 22, 1993, effective Jan. 3, 1994; paras. (b) & (d) revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; removed and reserved, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 1.197 Return of jurisdiction from the Board of Patent Appeals and Interferences; termination of proceedings.

(a) *Return of jurisdiction from the Board of Patent Appeals and Interferences.* Jurisdiction over an application or patent under *ex parte* reexamination proceeding passes to the examiner after a decision by the Board of Patent Appeals and Interferences upon transmittal of the file to the examiner, subject to appellant's right of appeal or other review, for such further action by appellant or by the examiner, as the condition of the application or patent under *ex parte* reexamination proceeding may require, to carry into effect the decision of the Board of Patent Appeals and Interferences.

(b) *Termination of proceedings.*

(1) Proceedings on an application are considered terminated by the dismissal of an appeal or the failure to timely file an appeal to the court or a civil action (§ 1.304) except:

(i) Where claims stand allowed in an application; or

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.10 Correspondence addresses.

Except as the Board may otherwise direct,

(a) *Appeals.* Correspondence in an application or a patent involved in an appeal (subparts B and C of this part) during the period beginning when an appeal docketing notice is issued and ending when a decision has been rendered by the Board, as well as any request for rehearing of a decision by the Board, shall be mailed to: Board of Patent Appeals and Interferences, United States Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. Notices of appeal, appeal briefs, reply briefs, requests for oral hearing, as well as all other correspondence in an application or a patent involved in an appeal to the Board for which an address is not otherwise specified, should be addressed as set out in § 1.1 (a)(1)(i) of this title.

(b) *Contested cases.* Mailed correspondence in contested cases (subpart D of this part) shall be sent to Mail Stop INTERFERENCE, Board of Patent Appeals and Interferences, United States Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.11 Ex parte communications in inter partes proceedings.

An *ex parte* communication about an inter partes reexamination (subpart C of this part) or about a contested case (subparts D and E of this part) with a Board member, or with a Board employee assigned to the proceeding, is not permitted.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.12 Citation of authority.

(a) Citations to authority must include:

(1) *For any United States Supreme Court decision*, a United States Reports citation.

(2) *For any decision other than a United States Supreme Court decision*, parallel citation to both the West Reporter System and to the United

States Patents Quarterly whenever the case is published in both. Other parallel citations are discouraged.

(3) *Pinpoint citations* whenever a specific holding or portion of an authority is invoked.

(b) Non-binding authority should be used sparingly. If the authority is not an authority of the Office and is not reproduced in one of the reporters listed in paragraph (a) of this section, a copy of the authority should be filed with the first paper in which it is cited.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.20 Fees.

(a) *Petition fee.* The fee for filing a petition under this part is: \$400.00

(b) *Appeal fees.* (1) For filing a notice of appeal from the examiner to the Board:

By a small entity (§ 1.27(a) of this title)	\$270.00
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By other than a small entity \$540.00

(2) In addition to the fee for filing a notice of appeal, for filing a brief in support of an appeal:

By a small entity (§ 1.27(a) of this title)	\$270.00
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By other than a small entity \$540.00

(3) For filing a request for an oral hearing before the Board in an appeal under 35 U.S.C. 134:

By a small entity (§ 1.27(a) .. \$540.00

By other than a small entity ... \$1,080.00

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004; paras. (b)(1) through (b)(3) revised, 69 FR 52604, Aug. 27, 2004, effective Oct. 1, 2004; para. (b)(3) corrected, 69 FR 55505, Sept. 15, 2004, effective Oct. 1, 2004; para. (a) revised, 69 FR 56481, Sept. 21, 2004, effective Nov. 22, 2004; para. (b) revised, 70 FR 3880, Jan. 27, 2005, effective Dec. 8, 2004; paras. (b)(1) through (b)(3) revised, 72 FR 46899, Aug. 22, 2007, effective Sept. 30, 2007; para. (b) revised, 73 FR 47534, Aug. 14, 2008, effective Oct. 2, 2008]

Subpart B — *Ex Parte Appeals*

§ 41.30 Definitions.

In addition to the definitions in § 41.2, the following definitions apply to proceedings under this subpart unless otherwise clear from the context:

subpart, the Board may relinquish jurisdiction to the examiner or take other appropriate action to permit completion of the file.

(c) Prior to the entry of a decision on the appeal by the Board, the Director may sua sponte order the proceeding remanded to the examiner.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.37 Appeal brief.

(a)(1)Appellant must file a brief under this section within two months from the date of filing the notice of appeal under § 41.31.

(2) The brief must be accompanied by the fee set forth in § 41.20(b)(2)

(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.

(c)(1)The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:

(i) *Real party in interest.* A statement identifying by name the real party in interest.

(ii) *Related appeals and interferences.* A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.

(iii) *Status of claims.* A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.

(iv) *Status of amendments.* A statement of the status of any amendment filed subsequent to final rejection.

(v) *Summary of claimed subject matter.* A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

(vi) *Grounds of rejection to be reviewed on appeal.* A concise statement of each ground of rejection presented for review.

(vii) *Argument.* The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points

out what a claim recites will not be considered an argument for separate patentability of the claim.

(viii) *Claims appendix.* An appendix containing a copy of the claims involved in the appeal.

(ix) *Evidence appendix.* An appendix containing copies of any evidence submitted pursuant to §§ 1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See § 41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

(x) *Related proceedings appendix.* An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See § 1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and § 41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of § 1.136 of this title for patent applications and § 1.550(c) of this title for *ex parte* reexamination proceedings.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.39 Examiner's answer.

(a)(1) The primary examiner may, within such time as may be directed by the Director, furnish a written answer to the appeal brief including such explanation of the invention claimed and of the refer-

ences relied upon and grounds of rejection as may be necessary, supplying a copy to appellant. If the primary examiner determines that the appeal does not comply with the provisions of §§ 41.31 and 41.37 or does not relate to an appealable action, the primary examiner shall make such determination of record.

(2) An examiner's answer may include a new ground of rejection.

(b) If an examiner's answer contains a rejection designated as a new ground of rejection, appellant must within two months from the date of the examiner's answer exercise one of the following two options to avoid *sua sponte* dismissal of the appeal as to the claims subject to the new ground of rejection:

(1) *Reopen prosecution.* Request that prosecution be reopened before the primary examiner by filing a reply under § 1.111 of this title with or without amendment or submission of affidavits (§§ 1.130, 1.131 or 1.132 of this title) or other evidence. Any amendment or submission of affidavits or other evidence must be relevant to the new ground of rejection. A request that complies with this paragraph will be entered and the application or the patent under *ex parte* reexamination will be reconsidered by the examiner under the provisions of § 1.112 of this title. Any request that prosecution be reopened under this paragraph will be treated as a request to withdraw the appeal.

(2) *Maintain appeal.* Request that the appeal be maintained by filing a reply brief as set forth in § 41.41. Such a reply brief must address each new ground of rejection as set forth in § 41.37(c)(1)(vii) and should follow the other requirements of a brief as set forth in § 41.37(c). A reply brief may not be accompanied by any amendment, affidavit (§§ 1.130, 1.131 or 1.132 of this title) or other evidence. If a reply brief filed pursuant to this section is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under paragraph (b)(1) of this section.

(c) Extensions of time under § 1.136 (a) of this title for patent applications are not applicable to the time period set forth in this section. See § 1.136 (b) of this title for extensions of time to reply for patent applications and § 1.550 (c) of this title for extensions of time to reply for *ex parte* reexamination proceedings.

ing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.”); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed. Cir. 1999) (“If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.”); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) (“Because ‘sufficient aeration’ was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.”); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound “inherently” anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound “inherently results in at least trace amounts of” the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<.

III. A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply

to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, “[a]n invitation to investigate is not an inherent disclosure” where a prior art reference “discloses no more than a broad genus of potential applications of its discoveries.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that “[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category” but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.<

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

In *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), the court affirmed a finding that a prior patent to a conical spout used primarily to dispense oil from an oil can inherently performed the functions recited in applicant's claim to a conical container top for dispensing popped popcorn. The examiner had asserted inherency based on the structural similarity between the patented spout and applicant's disclosed top, i.e., both structures had the same general shape. The court stated:

[N]othing in Schreiber's [applicant's] claim suggests that Schreiber's container is of a 'different shape' than Harz's [patent]. In fact, [] an embodiment according to Harz (Fig. 5) and the embodiment depicted in Fig. 1 of Schreiber's application have the same general shape. For that reason, the examiner was justified in concluding that the opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to 'allow [] several kernels of popped popcorn to pass through at the same time' and that the taper of Harz's conically shaped top is inherently of such a shape 'as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted to the container.' The examiner therefore correctly found that Harz established a *prima facie* case of anticipation.

In re Schreiber, 128 F.3d at 1478, 44 USPQ2d at 1432.

V. ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBIUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on '*prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

In *In re Fitzgerald*, the claims were directed to a self-locking screw-threaded fastener comprising a metallic threaded fastener having patches of crystallizable thermoplastic bonded thereto. The claim further specified that the thermoplastic had a reduced degree of crystallization shrinkage. The specification disclosed that the locking fastener was made by heating the metal fastener to melt a thermoplastic blank which is pressed against the metal. After the thermoplastic adheres to the metal fastener, the end product is cooled by quenching in water. The examiner made a rejection based on a U.S. patent to Barnes. Barnes taught a self-locking fastener in which the patch of thermoplastic was made by depositing thermoplastic powder on a metallic fastener which was then heated. The end product was cooled in ambient air, by cooling air or by contacting the fastener with a water trough. The court first noted that the two fasteners were identical or only slightly different from each other. "Both fasteners possess the same utility, employ the same crystallizable polymer (nylon 11), and have an adherent plastic patch formed by melting and then cooling the polymer." *Id.* at 596 n.1, 619 F.2d at 70 n.1. The court then noted that the Board had found that Barnes'

RELATED PROCEEDINGS APPENDIX

Serial No.: 09/888,943

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[NONE]